

US3092112 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:07:25

All time stamps listed in this document are displayed in GMT

US3092112

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

[Participant ID](#)

US3092112

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

US3092112

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3092112

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 00:44:46

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Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	HYPERTENSION
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)	

US3092112

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	TEMPOROMANDIBULAR JOINT DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

US3092112

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	INTERMITTENT GOUT (BILATERAL FEET)
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)	

US3092112

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	INTERMITTENT KIDNEY INFECTIONS
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)	

US3092112

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	MASSIVE STROKE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	CHRONIC BACK PAIN
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 (9)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	SPINAL FRACTURE
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 (10)

Data signed: (b) (4) 23 Mar 2021 22:43:56

Generated On: 09 Jun 2021 15:07:25

Condition	INTERMITTENT BILATERAL FOOT PAIN SECONDARY TO GOUT
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: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:20 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:20
Height (<i>xxx.x</i>)	163.8 cm
Weight (<i>xxx.x</i>)	92.1 kg
BMI (<i>xxx.x</i>)	34.32668 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Date of assessment (dd MMM yyyy) 11 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) UN UNK 2002

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:44:46

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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

Visit date (dd MMM yyyy)	11 AUG 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185481

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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)	11 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:20
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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)	11 AUG 2020
Time of assessment (00:00-23:59)	17:41 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:41
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 17:08 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 17:08

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	16:56 (24 HR)
Collection date and time (derived)	11 AUG 2020 16:56

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:52	11 AUG 2020 16:52
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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 15:07:25

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 11 AUG 2020 17:46

PC Open Date & Time 11 AUG 2020 17:28

PC Close Date & Time 11 AUG 2020 19:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

11 AUG 2020 20:53

PC Close Date & Time

12 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 20:14

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

97.8 °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

13 AUG 2020 22:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

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

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 00:03

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

11 AUG 2020 17:47

PC Open Date & Time

11 AUG 2020 17:28

PC Close Date & Time

11 AUG 2020 19:58

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

11 AUG 2020 20:53

PC Close Date & Time

12 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 20:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 22:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

17 AUG 2020 16:36

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 17:49
PC Open Date & Time	11 AUG 2020 17:28
PC Close Date & Time	11 AUG 2020 19:58

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 AUG 2020 20:53

PC Close Date & Time

12 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

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 ☒

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:15
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

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)

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 22:39
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

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
EAB) (1725)

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US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

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EAB) (1725)

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 16:37
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3092112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092112

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

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)	29 SEP 2020
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:07
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

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)	29 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:33
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3092112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 12:01 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 12:01

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

US3092112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	11:54 (24 HR)
Collection date and time (derived)	29 SEP 2020 11:54

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:32	29 SEP 2020 11:32
Nasopharyngeal Swab 2	No		

US3092112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

29 SEP 2020 12:42

PC Open Date & Time

29 SEP 2020 12:21

PC Close Date & Time

29 SEP 2020 14:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

29 SEP 2020 15:46

PC Close Date & Time

30 SEP 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

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

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

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

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

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.

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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.

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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

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

29 SEP 2020 12:45

PC Open Date & Time

29 SEP 2020 12:21

PC Close Date & Time

29 SEP 2020 14:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

29 SEP 2020 15:46

PC Close Date & Time

30 SEP 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

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Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 12:44
PC Open Date & Time	29 SEP 2020 12:21
PC Close Date & Time	29 SEP 2020 14:51

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Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 15:46

PC Close Date & Time

30 SEP 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

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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Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

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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Yes ☐

PC Time stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

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
EAB) (1725)

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Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092112

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092112

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

VM 10/20/20..ANSWERED

10/21/20

If Contact Not Made, please provide Comments

US3092112

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 11:47
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)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3092112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

30 OCT 2020 12:00

US3092112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:47

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	07 DEC 2020 23:59
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US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 138

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

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 <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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 <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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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°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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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°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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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°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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐ 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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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°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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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°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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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="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"/>

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3092112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092112

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 JAN 2021

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

Comments 1ST ATTEMPT MADE ON
12/29/20
If Contact Not Made, please provide Comments 2ND ATTEMPT MADE ON
12/30/20
3RD ATTEMPT MADE ON
01/04/21

US3092112

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments 1ST ATTEMPT MADE ON
01/25/21
If Contact Not Made, please provide Comments 2ND ATTEMPT MADE ON
01/26/21
3RD ATTEMPT MADE ON
01/27/21

US3092112

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Mar 2021 18:23:20

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092112

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:23:20

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3092112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

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.

US3092112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3092112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

Was Contact Attempted?

Yes ☒

No ☐

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

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

1ST ATTEMPT MADE ON

04/27/21

If Contact Not Made, please provide Comments

2ND ATTEMPT MADE ON

04/29/21

3RD ATTEMPT MADE ON

04/30/21

US3092112

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092112

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092112

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:07:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3092112

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

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3092112

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

Form: Unblinding

Generated On: 09 Jun 2021 15:07:25

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

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

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3092112

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3092112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:07:25

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3092112

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

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)	_____

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

AEID	USA-US086-2021-MRNA-1273-P30 1000009
Adverse event	WORSENING OF BACK 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)	1 FEB 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)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	1 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	6 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

Number of Days in ICU	5
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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SEE NARRATIVE. SUBJECT WILL REQUIRE SURGERY. A DATE HAS NOT BEEN SCHEDULED AND ADDITIONAL INFORMATION HAS NOT BEEN PROVIDED.

Narrative

US3092112

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SUBJECT WAS HOSPITALIZED
FOR BACK PAIN AND
BILATERAL FOOT PAIN WITH
EDEMA. SHE HAS HISTORY OF
INTERMITTENT GOUT AND
CHRONIC BACK PAIN AS
ADDED TO MEDICAL HISTORY
AFTER SPEAKING WITH
PATIENT. SHE IS CURRENTLY
GOING THROUGH PHYSICAL
THERAPY AT ENCOMPASS AND
WILL BE HAVING SPINAL
SURGERY IN 5-6 MONTHS. SHE
HAS HAD THE PAIN
INTERMITTENTLY AND WAS
MISDIAGNOSED UNTIL HER
RECENT HOSPITAL VISIT.

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

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

AEID	USA-US086-2021-MRNA-1273-P30 1000009
Adverse event	WORSENING OF BILATERAL FOOT PAIN (SECONDARY TO GOUT)
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)	1 FEB 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)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	01 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	06 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
<hr/>		
Persistent or significant disability or incapacity		False
<hr/>		
Congenital anomaly or birth defect		False
<hr/>		
Other medically important event		False
<hr/>		
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
<hr/>		
None		False
<hr/>		
Concomitant Medication		True
<hr/>		
Concomitant Procedure		False
<hr/>		
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative	SUBJECT REPORTED THAT SHE WAS HOSPITALIZED ON 1/FEB-6/FEB/2021 FOR BACK PAIN BILATERAL FOOT PAIN.	
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)		1
<hr/>		

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 02:22:24

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Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

AEID

Adverse event

LOW GRADE FEVER <100.4

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

AEID	USA-US086-2021-MRNA-1273-P30 1000009
Adverse event	BILATERAL FOOT EDEMA
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)	01 FEB 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)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	01 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	06 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

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	SUBJECT REPORTED THAT SHE WAS HOSPITALIZED ON 1/FEB-6/FEB/2021 FOR BILATERAL FOOT EDEMA AND BILATERAL FOOT PAIN.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 00:44:46

Generated On: 09 Jun 2021 15:07:25

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

Yes ☒

No ☐

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

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20/25

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

Name of Medication VALIUM

Prophylaxis Yes ☐
No ☒

Indication TEMPORMANDIBULAR JOINT
DYSFUNCTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1985	
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"/>

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

Name of Medication (LOMOTIL) DIPHENOXYLATE /
ATROPINE

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 2.5/0.025

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 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)		17 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication LOW GRADE FEVER <100.4

Dose per administration 220

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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US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

	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)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL FOOT PAIN/
BILATERAL
EDEMA/WORSENING OF BACK
PAIN

Dose per administration 4

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication BILATERAL FOOT PAIN

Dose per administration 50

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

THREE TIMES A DAY AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 00:58:53

Generated On: 09 Jun 2021 15:07:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 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"/>

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
20 FEB 2021	PHYSICAL THERAPY	Adverse Event	

US3092112

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:07:25

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

US3092112

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:07:25

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 ☐

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/FEB/2021 16:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/FEB/2021 16:15
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

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/MAR/2021 12:42
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

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/MAR/2021 06:18
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

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/MAR/2021 09:05
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

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/MAR/2021 06:23
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

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/MAR/2021 06:49
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

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (8)

Data signed: (b) (4) 29 Apr 2021 02:22:24

Generated On: 09 Jun 2021 15:07:25

SAEID	USA-US086-2021-MRNA-1273-P301000009
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	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/APR/2021 11:22
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

US3092112 (Prod: Global Medical Research - M3 Wake Research)

US3092112

Form: Participant Creation

Generated On: 09 Jun 2021 15:07:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'US3092112'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:21

US3092112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	11 Aug 2020 22:30:58

US3092112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:22

US3092112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	11 Aug 2020 22:30:58

US3092112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'SCRN'	System	11 Aug 2020 22:30:58

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:23

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '68'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'YEARS'	System	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '68'	System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Female (F)'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'I'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:07:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:21

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Aug 2020'	System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2020'	System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Amendment 2 (2)'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:22

US3092112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:07:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'I'	System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:02

US3092112

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:07:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:17:53

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 22:21:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:21:22
Data point term sent to Coder	System	17 Aug 2020 22:20:37
User entered 'Hypertension'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2015'	Marissa Cervenka (b) (4)	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2015'	System	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2015'	System	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:20:17

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Temporomandibular joint syndrome, LLT: Temporomandibular joint dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:22:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:22:22
Data point term sent to Coder	System	17 Aug 2020 22:21:38
User entered 'Temporomandibular Joint Dysfunction'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 1979'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 1979'	System	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '1979'	System	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:21:24

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 23:07:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 23:07:50
Data point term sent to Coder	System	17 Mar 2021 15:38:43
Coding entries removed.	Marissa Cervenka (b) (4)	17 Mar 2021 15:38:01
Signature has been broken.	Marissa Cervenka (b) (4)	17 Mar 2021 15:38:01
User entered 'INTERMITTENT GOUT (BILATERAL FEET)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	17 Mar 2021 15:38:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
Query 'Per DM CLR: Please review and reflect the specific body location of GOUT. Update Med History eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:43:46
User opened query 'Per DM CLR: Please review and reflect the specific body location of GOUT. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 02:13:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:23:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:23:23
Data point term sent to Coder	System	17 Aug 2020 22:22:39
User entered 'Intermittent Gout'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2016'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2016'	System	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2016'	System	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:21:53

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:24:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:24:25
Data point term sent to Coder	System	17 Aug 2020 22:23:39
User entered 'Sepsis'	Marissa Cervenka (b) (4)	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2016'	Marissa Cervenka (b) (4)	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2016'	Marissa Cervenka (b) (4)	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2016'	System	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2016'	System	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2016'	System	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2016'	System	17 Aug 2020 22:22:45

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
Query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral KINDEYS and the TYPE of INFECTION, if known. Update Med History eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:43:08
User opened query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral KINDEYS and the TYPE of INFECTION, if known. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 02:14:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Kidney infection, LLT: Kidney infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:18:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:18:21
Data point term sent to Coder	System	17 Aug 2020 22:28:45
User entered 'Intermittent Kidney Infections'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2016'	Marissa Cervenka (b) (4)	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 08:50:36
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 02:14:26
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2016'	System	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2016'	System	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:28:38

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 09:48:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:48:30
Data point term sent to Coder	System	17 Aug 2020 22:29:47
User entered 'Massive Stroke'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2008'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2008'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2008'	System	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2008'	System	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2008'	System	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2008'	System	17 Aug 2020 22:29:15

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:32:18
Data point term sent to Coder	System	17 Aug 2020 22:30:50
User entered 'Post-Menopausal'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2002'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2002'	System	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2002'	System	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Aug 2020 22:29:51

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
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: Chronic back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 15:19:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:19:45
Data point term sent to Coder	System	17 Mar 2021 15:19:23
User entered 'CHRONIC BACK PAIN'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:15
	(b) (4)	

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'UN UNK 2016'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2016'	System	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2016'	System	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 15:19:15

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Spinal fracture, LLT: Spinal fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 15:20:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:20:51
Data point term sent to Coder	System	17 Mar 2021 15:20:24
User entered 'SPINAL FRACTURE'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'I'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 15:19:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gouty pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:40:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:40:06
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Mar 2021 22:43:56
Data point term sent to Coder	System	17 Mar 2021 16:36:19
User entered 'INTERMITTENT BILATERAL FOOT PAIN SECONDARY TO GOUT'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'UN UNK 2016'	Marissa Cervenka (b) (4)	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'Jan 2016'	System	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '2016'	System	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered empty.	System	17 Mar 2021 16:35:38

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '15:20'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered '11 Aug 2020 15:20'	System	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '163.8' cm	(b) (4) Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '92.1' kg	(b) (4) Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
Amendment Manager: User entered '34.32668'	System	16 Sep 2020 23:52:41
User entered '34.3'	System	17 Aug 2020 22:31:46
DataPoint set to visible.	System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'kg/m2'	System	17 Aug 2020 22:31:46
DataPoint set to visible.	System	11 Aug 2020 22:36:40

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 11:37:09
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	26 Oct 2020 21:00:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	26 Oct 2020 21:00:21
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:33:35
User entered '36.3' C	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for Route of TEMPERATURE. thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:27:49
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for Route of TEMPERATURE. thanks ' answered with 'nd' (Site from DM).	destiny robinson (b) (4) (b) (4)	23 Nov 2020 19:51:22
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for Route of TEMPERATURE. thanks ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:37:14
User entered empty; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	26 Oct 2020 21:00:21
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 21:00:21
User entered '97'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'bpm'	System	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 21:00:21
User entered '14'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'breaths/min'	System	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 21:00:21
User entered '153'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'mmHg'	System	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 21:00:21
User entered '83'	Marissa Cervenka (b) (4)	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User entered 'mmHg'	System	17 Aug 2020 22:31:46

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35

US3092112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35

US3092112

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:05

US3092112

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:05

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'UN UNK 2002'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:07:25

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:33:52

US3092112

Folder: Screening

Form: Risk of Exposure

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

US3092112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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[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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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[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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Form: Risk of Exposure

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[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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

US3092112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

[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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

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 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'I'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

US3092112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

US3092112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '0'	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

US3092112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:07:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:12:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:37:58

US3092112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:14

US3092112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:14

US3092112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:14

US3092112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'VISIT1'	System	11 Aug 2020 22:32:14

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:29

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:43:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:43:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 21:14:29
User entered '185481' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 21:14:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:36

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:36

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:36

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:36

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Vicki Martinez (b) (4)	11 Aug 2020 22:32:36

US3092112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	(b) (4) destiny robinson (b) (4)	23 Nov 2020 19:53:47
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:18:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:38:52

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:07:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:07:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:07:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:07:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Pre-Dose (PREDOSE)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '15:20'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '11 Aug 2020 15:20'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '36.3' C	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '97'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'bpm'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '14'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'breaths/min'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '153'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '83'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:07:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:07:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Post-Dose (POSTDOSE)'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:43:54
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 22:53:06
User entered '17:41'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06
	(b) (4)	

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '11 Aug 2020 17:41'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '37.0' C	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '98'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'bpm'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '16'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'breaths/min'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '152'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '73'	Marissa Cervenka (b) (4)	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	17 Aug 2020 22:53:06

US3092112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:55:28

US3092112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:55:28

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	11 Aug 2020 22:43:20
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	11 Aug 2020 22:43:20
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Aug 2020 22:38:56
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	11 Aug 2020 22:38:56
	(b) (4)	

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Vicki Martinez (b) (4)	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Robert Miranda (b) (4)	11 Aug 2020 22:43:20
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	11 Aug 2020 22:38:56
	(b) (4)	

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '17:08'	Vicki Martinez (b) (4)	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '11 Aug 2020 17:08'	System	11 Aug 2020 22:43:20
User entered empty.	System	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Right Arm (RIGHT ARM)'	Vicki Martinez (b) (4)	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'ONCE'	System	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 22:38:56

US3092112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:56:30

US3092112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11 Aug 2020'	Marissa Cervenka (b) (4)	17 Aug 2020 22:56:30

US3092112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '16:56'	Marissa Cervenka (b) (4)	17 Aug 2020 22:56:30

US3092112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '11 Aug 2020 16:56'	System	17 Aug 2020 22:56:30

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:07:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 11AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 12AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 05:06:49
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 11AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 12AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'confirmed with lab. the correct date is 8/11/20' (Site from DM).	destiny robinson (b) (4) (b) (4)	14 Dec 2020 22:34:26
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 11AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 12AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:34:31
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (11AUG2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:34:16
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (11AUG2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:28:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:07:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) Marissa Cervenka (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '16:52'	Marissa Cervenka (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '11 Aug 2020 16:52'	System	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered empty.	System	17 Aug 2020 22:57:17

US3092112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	11 Aug 2020 22:39:06

US3092112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	11 Aug 2020 22:39:06

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:46:08', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'b26d04cc-8d89-464e-a7f1-474e85cbca90'	System	11 Aug 2020 22:46:45
User entered 'Yes (Y)'	System	11 Aug 2020 22:46:45

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:46:26', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'b26d04cc-8d89-464e-a7f1-474e85cbca90' User entered '98.6'	System	11 Aug 2020 22:46:45
	System	11 Aug 2020 22:46:45

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:46:34', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'b26d04cc-8d89-464e-a7f1-474e85cbca90'	System	11 Aug 2020 22:46:45
User entered 'No (N)'	System	11 Aug 2020 22:46:45

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:46:44', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'b26d04cc-8d89-464e-a7f1-474e85cbca90'	System	11 Aug 2020 22:46:45
User entered '11 Aug 2020 17:46'	System	11 Aug 2020 22:46:45

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 17:28'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 19:58'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 20:53'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 2'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:01:41', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '933fc117-647f-4cf9-9ee8-174b1b2cf8a3' User entered 'Yes (Y)'	System	13 Aug 2020 01:14:34
	System	13 Aug 2020 01:14:34

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:13:25', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '933fc117-647f-4cf9-9ee8-174b1b2cf8a3' User entered '99.0'	System	13 Aug 2020 01:14:34
	System	13 Aug 2020 01:14:34

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:14:15', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '933fc117-647f-4cf9-9ee8-174b1b2cf8a3'	System	13 Aug 2020 01:14:34
User entered 'No (N)'	System	13 Aug 2020 01:14:34

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:14:33', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '933fc117-647f-4cf9-9ee8-174b1b2cf8a3'	System	13 Aug 2020 01:14:34
User entered '12 Aug 2020 20:14'	System	13 Aug 2020 01:14:34

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 3'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:36:43', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'c62ab08b-1c3d-4e38-abd1-c2e80e81ca61' User entered 'Yes (Y)'	System	14 Aug 2020 03:37:14
	System	14 Aug 2020 03:37:14

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:36:55', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'c62ab08b-1c3d-4e38-abd1-c2e80e81ca61' User entered '97.8'	System	14 Aug 2020 03:37:14
	System	14 Aug 2020 03:37:14

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:04', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'c62ab08b-1c3d-4e38-abd1-c2e80e81ca61'	System	14 Aug 2020 03:37:14
User entered 'No (N)'	System	14 Aug 2020 03:37:14

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:12', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'c62ab08b-1c3d-4e38-abd1-c2e80e81ca61' User entered '13 Aug 2020 22:37'	System	14 Aug 2020 03:37:14
	System	14 Aug 2020 03:37:14

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 4'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 5'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-16T00:03:16', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e37b249-83a6-4480-81fd-a9a9bd0ba131' User entered 'Yes (Y)'	System	16 Aug 2020 05:03:51
	System	16 Aug 2020 05:03:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-16T00:02:42', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e37b249-83a6-4480-81fd-a9a9bd0ba131' User entered '98.0'	System	16 Aug 2020 05:03:51
	System	16 Aug 2020 05:03:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-16T00:02:49', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e37b249-83a6-4480-81fd-a9a9bd0ba131'	System	16 Aug 2020 05:03:51
User entered 'No (N)'	System	16 Aug 2020 05:03:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-16T00:03:49', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e37b249-83a6-4480-81fd-a9a9bd0ba131' User entered '16 Aug 2020 00:03'	System	16 Aug 2020 05:03:51
	System	16 Aug 2020 05:03:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 6'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 7'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:34:40', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e98dccc-dffd-45c3-8048-23f220e23a64' User entered 'Yes (Y)'	System	29 Sep 2020 17:37:53
	System	29 Sep 2020 17:37:53

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:34:58', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e98dccc-dffd-45c3-8048-23f220e23a64' User entered '97.9'	System	29 Sep 2020 17:37:53
	System	29 Sep 2020 17:37:53

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:32:48', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e98dccc-dffd-45c3-8048-23f220e23a64'	System	29 Sep 2020 17:37:53
User entered 'No (N)'	System	29 Sep 2020 17:37:53

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:35:06', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e98dccc-dffd-45c3-8048-23f220e23a64' User entered '17 Aug 2020 16:35'	System	29 Sep 2020 17:37:53
	System	29 Sep 2020 17:37:53

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:47:22', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'f07292e5-6089-4eef-a73f-66f5f1c06b07'	System	11 Aug 2020 22:47:54
User entered 'None (1)'	System	11 Aug 2020 22:47:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:47:34', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'f07292e5-6089-4eef-a73f-66f5f1c06b07'	System	11 Aug 2020 22:47:54
User entered 'No (N)'	System	11 Aug 2020 22:47:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:47:39', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'f07292e5-6089-4eef-a73f-66f5f1c06b07'	System	11 Aug 2020 22:47:54
User entered 'No (N)'	System	11 Aug 2020 22:47:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:47:45', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'f07292e5-6089-4eef-a73f-66f5f1c06b07'	System	11 Aug 2020 22:47:54
User entered 'None (1)'	System	11 Aug 2020 22:47:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:47:52', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'f07292e5-6089-4eef-a73f-66f5f1c06b07' User entered '11 Aug 2020 17:47'	System	11 Aug 2020 22:47:54
	System	11 Aug 2020 22:47:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 17:28'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 19:58'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 20:53'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 2'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:16:14', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e4443fd-3316-452a-a74c-2717584cbefa' User entered 'None (1)'	System	13 Aug 2020 01:16:59
	System	13 Aug 2020 01:16:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:16:31', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e4443fd-3316-452a-a74c-2717584cbefa' User entered 'No (N)'	System	13 Aug 2020 01:16:59
	System	13 Aug 2020 01:16:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:16:41', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e4443fd-3316-452a-a74c-2717584cbefa' User entered 'No (N)'	System	13 Aug 2020 01:16:59
	System	13 Aug 2020 01:16:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:16:51', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e4443fd-3316-452a-a74c-2717584cbefa' User entered 'None (1)'	System	13 Aug 2020 01:16:59
	System	13 Aug 2020 01:16:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:16:56', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1e4443fd-3316-452a-a74c-2717584cbefa'	System	13 Aug 2020 01:16:59
User entered '12 Aug 2020 20:16'	System	13 Aug 2020 01:16:59

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 3'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:37', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '13270bf4-1840-484a-8b07-ea90d4c6e396'	System	14 Aug 2020 03:38:00
User entered 'None (1)'	System	14 Aug 2020 03:38:00

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:42', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '13270bf4-1840-484a-8b07-ea90d4c6e396'	System	14 Aug 2020 03:38:00
User entered 'No (N)'	System	14 Aug 2020 03:38:00

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:46', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '13270bf4-1840-484a-8b07-ea90d4c6e396'	System	14 Aug 2020 03:38:00
User entered 'No (N)'	System	14 Aug 2020 03:38:00

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:53', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '13270bf4-1840-484a-8b07-ea90d4c6e396'	System	14 Aug 2020 03:38:00
User entered 'None (1)'	System	14 Aug 2020 03:38:00

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:37:57', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '13270bf4-1840-484a-8b07-ea90d4c6e396' User entered '13 Aug 2020 22:37'	System	14 Aug 2020 03:38:00
	System	14 Aug 2020 03:38:00

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 4'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 5'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 6'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 7'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:35:16', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '5cb02c96-03c0-4c56-9cd4-075740fd9162'	System	29 Sep 2020 17:37:54
User entered 'None (1)'	System	29 Sep 2020 17:37:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:35:20', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '5cb02c96-03c0-4c56-9cd4-075740fd9162'	System	29 Sep 2020 17:37:54
User entered 'No (N)'	System	29 Sep 2020 17:37:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:35:25', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '5cb02c96-03c0-4c56-9cd4-075740fd9162' User entered 'No (N)'	System	29 Sep 2020 17:37:54
	System	29 Sep 2020 17:37:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:35:45', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '5cb02c96-03c0-4c56-9cd4-075740fd9162' User entered 'None (1)'	System	29 Sep 2020 17:37:54
	System	29 Sep 2020 17:37:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:36:10', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '5cb02c96-03c0-4c56-9cd4-075740fd9162' User entered '17 Aug 2020 16:36'	System	29 Sep 2020 17:37:54
	System	29 Sep 2020 17:37:54

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:20', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'None (0)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:25', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'None (0)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:29', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'None (0)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:41', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'None (0)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:45', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'None (0)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:49', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'None (0)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:48:58', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered 'No (N)'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-11T17:49:02', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '1de1b996-89f3-45a5-99c7-2c75dcb2d29e' User entered '11 Aug 2020 17:49'	System	11 Aug 2020 22:49:06
	System	11 Aug 2020 22:49:06

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 17:28'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 19:58'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '11 Aug 2020 20:53'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 2'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:14:43', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6' User entered 'None (0)'	System	13 Aug 2020 01:15:26
	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:14:47', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6' User entered 'None (0)'	System	13 Aug 2020 01:15:26
	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:14:53', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6'	System	13 Aug 2020 01:15:26
User entered 'None (0)'	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:14:59', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6' User entered 'None (0)'	System	13 Aug 2020 01:15:26
	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:15:04', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6' User entered 'None (0)'	System	13 Aug 2020 01:15:26
	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:15:07', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6'	System	13 Aug 2020 01:15:26
User entered 'None (0)'	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:15:15', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6'	System	13 Aug 2020 01:15:26
User entered 'No (N)'	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-12T20:15:24', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '272787d5-aa38-4707-96a8-19d598c295d6'	System	13 Aug 2020 01:15:26
User entered '12 Aug 2020 20:15'	System	13 Aug 2020 01:15:26

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 3'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:38:06', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'None (0)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:38:23', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'None (0)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:38:50', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'None (0)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:39:00', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'None (0)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:39:06', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'None (0)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:39:11', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'None (0)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:39:20', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered 'No (N)'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-13T22:39:35', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '20e115e0-1cad-4d18-a5a1-229993d10a2b' User entered '13 Aug 2020 22:39'	System	14 Aug 2020 03:39:39
	System	14 Aug 2020 03:39:39

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 4'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 5'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 6'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 7'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:36:19', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'None (0)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:36:36', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'None (0)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:36:48', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'None (0)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:36:54', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'None (0)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:37:00', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'None (0)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:37:06', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'None (0)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:37:15', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered 'No (N)'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-08-17T16:37:19', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '66edb1d5-ece4-4b37-a60f-5fb6e0f018ed' User entered '17 Aug 2020 16:37'	System	29 Sep 2020 17:37:57
	System	29 Sep 2020 17:37:57

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:43:20

US3092112

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:54:35
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 18:14:48

US3092112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:54:35
User entered '18 Aug 2020'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 18:14:48

US3092112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:54:35
User entered 'Contact Not Made (CONTACT NOT MADE)'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 18:14:48

US3092112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:54:35
User entered 'Attempt call made to subject, phone rang several times, no voicemail'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 18:14:48

US3092112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 11:32:50

US3092112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	18 Sep 2020 11:32:50

US3092112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:50:44

US3092112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:50:44

US3092112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:50:44

US3092112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:50:44

US3092112

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 11:33:02

US3092112

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	18 Sep 2020 11:33:02

US3092112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:52:28

US3092112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 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)	02 Nov 2020 07:08:36
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed and date is correct ' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 20:53:00
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Oct 2020 20:52:28
User entered '22 Sep 2020'	(b) (4), (b) (6)	30 Oct 2020 20:52:28

US3092112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:52:28

US3092112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:52:28

US3092112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 11:33:11

US3092112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	18 Sep 2020 11:33:11

US3092112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:09:52

US3092112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 04:54:37
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit out of window.' (Site from System).	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:10:05
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 17:09:52
User entered '29 Sep 2020'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:09:52

US3092112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	29 Sep 2020 17:09:52

US3092112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'VISIT2'	System	29 Sep 2020 17:09:52

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Pre-Dose (PREDOSE)'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '29 Sep 2020'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11:07'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '29 Sep 2020 11:07'	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '98.4' F	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Oral (Oral)'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '72'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'bpm'	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '17'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'breaths/min'	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '119'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '64'	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Post-Dose (POSTDOSE)'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
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 Sep 2020 18:24:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 17:12:22
	Catina Adams (b) (4)	29 Sep 2020 17:12:22
	(b) (4)	

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '29 Sep 2020' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '12:33' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '29 Sep 2020 12:33'	System	29 Sep 2020 18:24:54
User entered empty.	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '98.6' F reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '77' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'bpm'	System	29 Sep 2020 18:24:54
User entered empty.	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '16' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'breaths/min'	System	29 Sep 2020 18:24:54
User entered empty.	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '140' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	29 Sep 2020 18:24:54
User entered empty.	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '75' reason for change: Data Entry Error	Catina Adams (b) (4)	29 Sep 2020 18:24:54
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	29 Sep 2020 18:24:54
User entered empty.	System	29 Sep 2020 17:12:22

US3092112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:10:27

US3092112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '29 Sep 2020'	Catina Adams (b) (4)	29 Sep 2020 17:10:27

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	Catina Adams (b) (4)	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '29 Sep 2020'	Catina Adams (b) (4)	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '12:01'	Catina Adams (b) (4)	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Right Arm (RIGHT ARM)'	Catina Adams (b) (4)	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'ONCE'	System	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:07:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 17:11:07

US3092112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:15:50

US3092112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '29 Sep 2020'	Catina Adams (b) (4)	29 Sep 2020 17:15:50

US3092112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11:54'	Catina Adams (b) (4)	29 Sep 2020 17:15:50

US3092112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '29 Sep 2020 11:54'	System	29 Sep 2020 17:15:50

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:07:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '29 Sep 2020'	Catina Adams (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11:32'	Catina Adams (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '29 Sep 2020 11:32'	System	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:48:57
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:48:57
User entered '11:32'	Catina Adams (b) (4) (b) (4)	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered empty.	System	31 Dec 2020 17:48:57
User entered '29 Sep 2020 11:32'	System	29 Sep 2020 17:16:16

US3092112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Sep 2020 17:16:24

US3092112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	29 Sep 2020 17:16:24

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:41:54', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '19882f4e-8cc4-4d5f-b6ed-f64a25f0fdd2'	System	29 Sep 2020 17:43:10
User entered 'Yes (Y)'	System	29 Sep 2020 17:43:10

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:42:39', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '19882f4e-8cc4-4d5f-b6ed-f64a25f0fdd2'	System	29 Sep 2020 17:43:10
User entered '98.6'	System	29 Sep 2020 17:43:10

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:42:46', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '19882f4e-8cc4-4d5f-b6ed-f64a25f0fdd2'	System	29 Sep 2020 17:43:10
User entered 'No (N)'	System	29 Sep 2020 17:43:10

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:42:57', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '19882f4e-8cc4-4d5f-b6ed-f64a25f0fdd2'	System	29 Sep 2020 17:43:10
User entered '29 Sep 2020 12:42'	System	29 Sep 2020 17:43:10

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 14:51'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 15:46'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 2'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 3'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 4'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 5'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 6'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 7'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:44:23', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'e3ad2ee8-f70d-4c86-946c-c567b54fe1f3' User entered 'None (1)'	System	29 Sep 2020 17:45:14
	System	29 Sep 2020 17:45:14

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:44:39', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'e3ad2ee8-f70d-4c86-946c-c567b54fe1f3' User entered 'No (N)'	System	29 Sep 2020 17:45:14
	System	29 Sep 2020 17:45:14

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:44:47', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'e3ad2ee8-f70d-4c86-946c-c567b54fe1f3' User entered 'No (N)'	System	29 Sep 2020 17:45:14
	System	29 Sep 2020 17:45:14

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:44:56', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'e3ad2ee8-f70d-4c86-946c-c567b54fe1f3'	System	29 Sep 2020 17:45:14
User entered 'None (1)'	System	29 Sep 2020 17:45:14

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:45:01', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: 'e3ad2ee8-f70d-4c86-946c-c567b54fe1f3' User entered '29 Sep 2020 12:45'	System	29 Sep 2020 17:45:14
	System	29 Sep 2020 17:45:14

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 14:51'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 15:46'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 2'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 3'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 4'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 5'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 6'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 7'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:43:27', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'None (0)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:43:32', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'None (0)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:43:39', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'None (0)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:43:47', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'None (0)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:43:51', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'None (0)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:43:54', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'None (0)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:44:01', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered 'No (N)'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B9B9ABA6-9B53-4CB8-980E-D10A64E95726)', Time: '2020-09-29T12:44:10', User OID: 'PatientReportedOutcome (US3092112)', ODM File OID: '921fb577-35b0-4444-9ba2-1eedbd6d11ea' User entered '29 Sep 2020 12:44'	System	29 Sep 2020 17:44:24
	System	29 Sep 2020 17:44:24

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 14:51'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '29 Sep 2020 15:46'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 2'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 3'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 4'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 5'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 6'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
Data entry locked.	System	29 Sep 2020 17:11:07
User entered 'Day 7'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 17:11:07

US3092112

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:07:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:43:51
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 17:11:07

US3092112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 19:37:09

US3092112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '6 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 19:37:09

US3092112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 19:37:09

US3092112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	destiny robinson (b) (4)	06 Oct 2020 19:37:09

US3092112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 19:37:13

US3092112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	06 Oct 2020 19:37:13

US3092112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Oct 2020 16:03:00

US3092112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '13 Oct 2020'	destiny robinson (b) (4)	16 Oct 2020 16:03:00

US3092112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Oct 2020 16:03:00

US3092112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	destiny robinson (b) (4)	16 Oct 2020 16:03:00

US3092112

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	16 Oct 2020 16:03:05

US3092112

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	16 Oct 2020 16:03:05

US3092112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	21 Oct 2020 14:50:10

US3092112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '20 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	21 Oct 2020 14:50:10

US3092112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	21 Oct 2020 14:50:10

US3092112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'vm 10/20/20..answereed 10/21/20'	(b) (4) destiny robinson (b) (4) (b) (4)	21 Oct 2020 14:50:10

US3092112

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	destiny robinson (b) (4)	21 Oct 2020 14:50:13

US3092112

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	21 Oct 2020 14:50:13

US3092112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:08

US3092112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:08

US3092112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:08

US3092112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:07:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'VISIT3'	System	30 Oct 2020 20:49:08

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '11:47'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '30 Oct 2020 11:47'	System	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '95'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'bpm'	System	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'breaths/min'	System	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '103'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '69'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'mmHg'	System	30 Oct 2020 20:49:53

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25

US3092112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:07:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25

US3092112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:08

US3092112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:07:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:08

US3092112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:28

US3092112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:28

US3092112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '12:00'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:28

US3092112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered '30 Oct 2020 12:00'	System	30 Oct 2020 20:50:28

US3092112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:33

US3092112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	30 Oct 2020 20:50:33

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 64'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[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)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Have you been exposed to someone with 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)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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US3092112

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 71'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

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[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)
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US3092112

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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Audit	User	Time (GMT)
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US3092112

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:07:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092112

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Vomiting](#)

Audit	User	Time (GMT)
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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 22:43:20

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[Patient Cloud Close Date & Time](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 22:43:20

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TIMEPOINT

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 78'	System	11 Aug 2020 22:43:20

US3092112

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Chills](#)

Audit	User	Time (GMT)
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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 92'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092112

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:07:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092112

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Nausea](#)

Audit	User	Time (GMT)
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 22:43:20

US3092112

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[Patient Cloud Close Date & Time](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 22:43:20

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TIMEPOINT

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered 'Day 99'	System	11 Aug 2020 22:43:20

US3092112

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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[Chills](#)

Audit	User	Time (GMT)
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US3092112

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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US3092112

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092112

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
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US3092112

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092112

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 22:43:20

US3092112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:57:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:24:11
Data entry locked.	System	11 Aug 2020 22:43:20
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 22:43:20

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:24:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:24:11

US3092112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:07:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:24:11
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:24:11

US3092112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:56:03

US3092112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:56:03

US3092112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:56:03

US3092112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:56:03

US3092112

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:56:07

US3092112

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:07:25
User entered 'I'	System	23 Nov 2020 22:56:07

US3092112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:29:32

US3092112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:29:32

US3092112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:29:32

US3092112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '1st attempt made on 12/29/20	(b) (4)	05 Jan 2021 22:29:32
2nd attempt made on 12/30/20	(b) (4), (b) (6)	
3rd attempt made on 01/04/21'		

US3092112

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:29:38

US3092112

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User entered 'I'	System	05 Jan 2021 22:29:38

US3092112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:27:29

US3092112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:27:29

US3092112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:27:29

US3092112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered '1st attempt made on 01/25/21	(b) (4)	27 Jan 2021 17:27:29
2nd attempt made on 01/26/21	(b) (4), (b) (6)	
3rd attempt made on 01/27/21'		

US3092112

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:27:34

US3092112

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User entered 'I'	System	27 Jan 2021 17:27:34

US3092112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:35:21

US3092112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:35:21

US3092112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:35:21

US3092112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:35:21

US3092112

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:36:59

US3092112

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:17:03
User entered 'I'	System	05 Mar 2021 22:36:59

US3092112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 22:05:33

US3092112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 22:05:33

US3092112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 22:05:52

US3092112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 14:13:09
User entered '30 Apr 2021'		30 Apr 2021 22:05:52

US3092112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 14:13:09
User entered 'Contact Made (CONTACT MADE)'		30 Apr 2021 22:05:52

US3092112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:07:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered '1st attempt made on 04/27/21 2nd attempt made on 04/29/21 3rd attempt made on 04/30/21' reason for change: Data Entry Error User entered empty.	(b) (4), (b) (6)	03 May 2021 14:13:09
		30 Apr 2021 22:05:52

US3092112

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 22:06:18

US3092112

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:07:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 22:06:18

US3092112

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:07:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:24
DataPoint Verified.		06 Apr 2021 14:44:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:03:00

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	23 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)	23 Nov 2020 23:06:07
Data point term sent to Coder	System	23 Nov 2020 23:05:40
User entered 'DIARRHEA'	(b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User entered empty.	System	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 08:11:45
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Updated end date' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:52:51
User entered 'No (N)' reason for change: Data Entry Error		17 Mar 2021 13:51:21
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).		09 Jan 2021 06:34:39
User entered 'Yes (Y)'		23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 13:51:21
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User entered empty.	System	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Marissa Cervenka (b) (4)	17 Mar 2021 17:20:12
User entered 'Related (RELATED)'	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Per CDM: AE started after the first dose yet Not applicable is selected for Relationship to Study Procedure. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 08:12:24
Query 'Per CDM: AE started after the first dose yet Not applicable is selected for Relationship to Study Procedure. Please review and update as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:19:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:19:19
User opened query 'Per CDM: AE started after the first dose yet Not applicable is selected for Relationship to Study Procedure. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:15:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:51:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User entered '0'	System	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55
User entered '0'	System	23 Nov 2020 23:04:47

US3092112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 23:06:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 23:06:59
Data point term sent to Coder	System	23 Nov 2020 23:06:40
User entered 'NAUSEA'	(b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User entered empty.	System	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User entered empty.	System	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Per CDM: AE started after the first dose yet Not applicable is selected for Relationship to Study Procedure. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 08:15:06
Query 'Per CDM: AE started after the first dose yet Not applicable is selected for Relationship to Study Procedure. Please review and update as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:20:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:20:33
User opened query 'Per CDM: AE started after the first dose yet Not applicable is selected for Relationship to Study Procedure. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:15:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User entered '0'	System	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45
User entered '0'	System	23 Nov 2020 23:06:06

US3092112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:45

US3092112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'SAE states subject had Foot Pain as well, please review and AE to EDC and AE log in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:10:58
Query 'SAE states subject had Foot Pain as well, please review and AE to EDC and AE log in source.' answered with 'MH LOG AND AE LOG UPDATED IN SOURCE AND ECRF. ' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:36:36
User opened query 'SAE states subject had Foot Pain as well, please review and AE to EDC and AE log in source.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:05:51
DataPoint Verified.		02 Mar 2021 20:31:39
Reviewed for Safety.		25 Feb 2021 21:03:01
User entered		25 Feb 2021 21:02:49
'USA-US086-2021-mRNA-1273-P301000009'		
User entered 'New'		25 Feb 2021 21:02:49

US3092112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:02:42
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: Back pain aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 23:20:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 23:20:18
Data point term sent to Coder	System	29 Mar 2021 23:19:34
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 23:19:03
User entered 'WORSENING OF BACK PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 23:19:03
User closed query 'PV Query: As chronic back pain is part of medical history, please confirm if event term should be updated to worsening back pain instead.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 16:45:02
Query 'PV Query: As chronic back pain is part of medical history, please confirm if event term should be updated to worsening back pain instead.' answered with 'UPDATED' (Site from Safety).	Marissa Cervenka (b) (4)	17 Mar 2021 16:36:46
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: Back pain aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:14:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:14:45
Data point term sent to Coder	System	17 Mar 2021 15:14:17
DataPoint Un-verified.	Marissa Cervenka (b) (4)	17 Mar 2021 15:13:26
Coding entries removed.	(b) (4)	
	Marissa Cervenka (b) (4)	17 Mar 2021 15:13:26
User entered 'WORSENING OF CHRONIC BACK PAIN' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	17 Mar 2021 15:13:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As chronic back pain is part of medical history, please confirm if event term should be updated to worsening back pain instead.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 13:48:39
	(b) (4), (b) (6)	02 Mar 2021 20:31:39
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 18:42:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 18:42:00
Data point term sent to Coder	System	25 Feb 2021 18:40:53
User entered 'Back pain'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Should be no as it is a SAE? Please review and update.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:10:39 06 Apr 2021 15:02:38
Query 'Should be no as it is a SAE? Please review and update.' answered with 'PER CRF COMPLETION GUIDELINES THIS APPEARS TO MEET DEFINITION OF MEDICALLY ATTENDED. PLEASE CONFIRM. ' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:42:37
User opened query 'Should be no as it is a SAE? Please review and update.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:00:47 02 Mar 2021 21:00:20
DataPoint Verified.		02 Mar 2021 20:54:16
Query 'Should this NO and Yes for SAE as the subject was hospitalized? Please review and correct.' canceled (Site from CRA).		02 Mar 2021 20:54:14
User opened query 'Should this NO and Yes for SAE as the subject was hospitalized? Please review and correct.' (Site from CRA). DataPoint Un-verified.		02 Mar 2021 20:53:32 02 Mar 2021 20:52:46
DataPoint Verified.		02 Mar 2021 20:31:39
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	02 Mar 2021 20:54:19
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 20:52:44
DataPoint Verified.		02 Mar 2021 20:31:39
User entered 'No (N)'	destiny robinson (b) (4)	25 Feb 2021 18:39:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

US3092112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '1 Feb 2021'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered empty.	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

US3092112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:05:17
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		18 Mar 2021 16:45:33
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'DONE' (Site from Safety).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:25
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:16
User entered 'No (N)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:47:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 19:28:02
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 19:27:29
User entered 'Yes (Y)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 19:27:29
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:58:20
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 17:27:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	17 Mar 2021 17:27:34
User entered '06 Feb 2021' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:27:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 17:24:20
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:58:50
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	17 Mar 2021 16:58:50
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 16:58:16
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:16
User entered '6 Feb 2021' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 19:28:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 19:28:02
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	25 Feb 2021 19:28:02
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User entered '6 Feb 2021'	System	25 Feb 2021 18:39:55
	destiny robinson (b) (4)	25 Feb 2021 18:39:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered empty.	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:06:49
User closed query 'Does not match source AE log, please review and update accordingly' (Site from CRA).		06 Apr 2021 15:06:48
Query 'Does not match source AE log, please review and update accordingly' answered with 'SOURCE CORRESPONDS TO ECRF' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:14:28
User opened query 'Does not match source AE log, please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:02:30
Query 'Does not match, please have PI/Sub I review and update accordingly.' canceled (Site from CRA).		02 Mar 2021 21:02:22
User opened query 'Does not match, please have PI/Sub I review and update accordingly.' (Site from CRA).		02 Mar 2021 21:01:21
DataPoint Un-verified.		02 Mar 2021 21:00:12
DataPoint Verified.		02 Mar 2021 20:31:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Does not match source AE log, please review and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:07:49
Query 'Does not match source AE log, please review and update accordingly.' answered with 'SOURCE CORRECTED' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:14:41
User opened query 'Does not match source AE log, please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:02:12
DataPoint Verified.		02 Mar 2021 20:31:39
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Feb 2021 19:28:02
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Feb 2021 18:39:55
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		25 Feb 2021 19:28:02
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		25 Feb 2021 19:28:02
User entered '1' reason for change: Data Entry Error destiny robinson	(b) (4)	25 Feb 2021 19:28:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	25 Feb 2021 18:39:55
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '1 Feb 2021'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '6 Feb 2021'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	25 Feb 2021 19:28:02
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	25 Feb 2021 19:28:02
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	25 Feb 2021 18:39:55
User entered '5'	destiny robinson (b) (4)	25 Feb 2021 18:39:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'Not Related (NOT RELATED)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'Not Related (NOT RELATED)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:06:55
User closed query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		18 Mar 2021 16:45:50
Query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:23:28
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:16
User opened query 'PV Query: As the last dose of study drug was given on 29 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:47:11
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'None (NONE)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 01:30:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 23:19:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		29 Mar 2021 11:34:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		18 Mar 2021 16:46:31
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'CONMEDS LISTED ON CONMED LOG' (Site from Safety).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:08:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:48:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'I'	destiny robinson (b) (4)	25 Feb 2021 18:39:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered '0'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:07:12
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		18 Mar 2021 16:46:37
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:27:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:24:20
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'DONE' (Site from Safety).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 17:23:38
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:58:50
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:47:30
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:07:10
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	17 Mar 2021 17:30:02
DataPoint Un-verified.	Marissa Cervenka (b) (4)	17 Mar 2021 17:30:02
User entered 'SEE NARRATIVE. SUBJECT WILL REQUIRE SURGERY. A DATE HAS NOT BEEN SCHEDULED AND ADDITIONAL INFORMATION HAS NOT BEEN PROVIDED.'	(b) (4)	
reason for change: Data Entry Error	Marissa Cervenka (b) (4)	17 Mar 2021 17:30:02
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
DataPoint Verified.	System	17 Mar 2021 17:27:34
	(b) (4), (b) (6)	02 Mar 2021 20:31:39
User entered empty.	destiny robinson (b) (4)	25 Feb 2021 18:39:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Per CDM CLR re-query: Per response please update the Conproc page once the details are available. Thank you.' (Site from DM).	(b) (4)	28 Apr 2021 06:56:40
Query 'Per CDM CLR re-query: Per response please update the Conproc page once the details are available. Thank you.' answered with 'UPDATED EDC' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per CDM CLR re-query: Per response please update the Conproc page once the details are available. Thank you.' (Site from DM).		
User closed query 'Per DM CLR: Narrative = PHYSICAL THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).		
User closed query 'PV Query: Please confirm if bilateral foot pain with edema should be reported as separate event.' (Site from Safety).		
User closed query 'PV Query: Please add chronic back pain to medical history eCRF.' (Site from Safety).		
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = PHYSICAL THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'SUBJECT INFORMED SITE THAT SHE WAS DOING PT BUT DETAILS HAVE NOT BEEN PROVIDED. ' (Site from DM).	Marissa Cervenka (b) (4)	17 Mar 2021 17:34:11
Query 'PV Query: Please confirm if bilateral foot pain with edema should be reported as separate event.' answered with 'DONE' (Site from Safety).	Marissa Cervenka (b) (4)	17 Mar 2021 17:31:52
Query 'PV Query: Please add chronic back pain to medical history eCRF.' answered with 'DONE' (Site from Safety).	Marissa Cervenka (b) (4)	17 Mar 2021 17:31:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'THE ONLY RECORDS RECEIVED ARE X-RAY PHOTOS' (Site from Safety).	Marissa Cervenka (b) (4)	17 Mar 2021 17:31:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'RECORDS PROVIDED DO NOT INCLUDE COVID-19 TESTING' (Site from Safety).	Marissa Cervenka (b) (4)	17 Mar 2021 17:31:01
User opened query 'Per DM CLR: Narrative = PHYSICAL THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:56:04
User opened query 'PV Query: Please confirm if bilateral foot pain with edema should be reported as separate event.' (Site from Safety).		03 Mar 2021 13:48:52
User opened query 'PV Query: Please add chronic back pain to medical history eCRF.' (Site from Safety).		03 Mar 2021 13:48:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:48:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		03 Mar 2021 13:47:20
DataPoint Verified.		02 Mar 2021 20:31:39
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 19:32:28
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 19:32:28
User entered 'subject was hospitalized for back pain and bilateral foot pain with edema. she has history of intermittent gout and chronic back pain as added to medical history after speaking with patient. she is currently going through physical therapy at encompass and will be having spinal surgery in 5-6 months. she has had the pain intermitently and was misdiagnosed until her recent hospial visit.' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 19:32:28
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 18:39:55
User entered empty.	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 18:39:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:22:25
DataPoint Verified.		06 Apr 2021 15:18:17
User entered 'USA-US086-2021-mRNA-1273-P301000009'		18 Mar 2021 16:42:20

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:18:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gouty pain - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:07:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:07:54
	(b) (4)	
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.	(b) (4), (b) (6)	31 Mar 2021 01:31:41
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout aggravated - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 14:03:06
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 14:03:06
	(b) (4)	
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.	(b) (4), (b) (6)	29 Mar 2021 23:22:12
' answered with 'UPDATED' (Site from DM).		
Data point term sent to Coder	System	29 Mar 2021 23:21:38
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 23:20:47
User entered 'WORSENING OF BILATERAL FOOT PAIN (SECONDARY TO GOUT)' reason for change: Data Entry Error		29 Mar 2021 23:20:47
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.		29 Mar 2021 11:35:18
' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The event term 'BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)' contains multiple event terms. Please consider separating them into separate events' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:21:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gouty pain - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 07:55:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 07:55:30
Data point term sent to Coder	System	24 Mar 2021 00:45:02
User closed query 'CDM Coding, please split the term (BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)) into two separate records, as 'BILATERAL FOOT PAIN' and 'BILATERAL FOOT EDEMA' reporting each term separately with all relevant information e.g. start and stop dates etc.' (Site from System).	System	24 Mar 2021 00:44:44
Query 'CDM Coding, please split the term (BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)) into two separate records, as 'BILATERAL FOOT PAIN' and 'BILATERAL FOOT EDEMA' reporting each term separately with all relevant information e.g. start and stop dates etc.' answered with 'Separated updated.' (Site from System).	Catina Adams (b) (4)	24 Mar 2021 00:44:44
Query 'PV Query: The event term 'BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)' contains multiple event terms. Please consider separating them into separate events' answered with 'Separated updated' (Site from Safety).	Catina Adams (b) (4)	24 Mar 2021 00:44:30
Data point term sent to Coder	System	24 Mar 2021 00:35:46
User entered 'BILATERAL FOOT PAIN (SECONDARY TO GOUT)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:35:10
User opened query 'PV Query: The event term 'BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)' contains multiple event terms. Please consider separating them into separate events' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:55:47

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding, please split the term (BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)) into two separate records, as 'BILATERAL FOOT PAIN' and 'BILATERAL FOOT EDEMA' reporting each term separately with all relevant information e.g. start and stop dates etc.' (Site from System). Data point term sent to Coder	Coder Import (b) (4) (b) (4)	18 Mar 2021 14:25:39
User entered 'BILATERAL FOOT PAIN WITH EDEMA (SECONDARY TO GOUT)' reason for change: Data Entry Error Data point term sent to Coder	System Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:18:22 17 Mar 2021 15:18:01
User entered 'BILATERAL FOOT PAIN WITH EDEMA'	System Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:12:13 17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:18:21
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:19:53
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:19:56
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:19:58
User entered '1 Feb 2021'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:00
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:03
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:05
User entered '06 Feb 2021'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:07
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

Severity

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity or remove if a duplicate from baseline medical history. Else, clarify. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:13:43
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity or remove if a duplicate from baseline medical history. Else, clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 15:19:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 13:55:18
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity or remove if a duplicate from baseline medical history. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:54:46
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 07:42:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 13:54:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 07:42:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	29 Mar 2021 23:22:04
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 15:18:01
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 15:18:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:19:44
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:10
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:11
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:18
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:14
User entered '01 Feb 2021'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:16
User entered '06 Feb 2021'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:20
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Mar 2021 15:18:01
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		17 Mar 2021 15:18:01
User entered 'No (N)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:18:01
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Mar 2021 15:11:32
User entered 'Unknown (UNK)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:23
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:24
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:26
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:28
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:30
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:33
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:35
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:37
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:39
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

US3092112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:45
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:47
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 15:18:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 15:18:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:18:01
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 15:11:32
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[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 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:52
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:20:55
User closed query 'PV Query: If possible, please provide X-ray photos ' (Site from Safety).		25 Mar 2021 13:22:57
Query 'PV Query: If possible, please provide X-ray photos ' answered with 'X-ray in chart.' (Site from Safety).	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:33:04
User opened query 'PV Query: If possible, please provide X-ray photos ' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:55:31
User entered 'SUBJECT REPORTED THAT SHE WAS HOSPITALIZED ON 1/FEB-6/FEB/2021 FOR BACK PAIN BILATERAL FOOT PAIN.'	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 15:11:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Low grade fever - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 07:29:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 07:29:33
Data point term sent to Coder	System	17 Mar 2021 17:18:43
User entered 'LOW GRADE FEVER <100.4'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '18 Oct 2020'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User entered empty.	System	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '19 Oct 2020'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User entered empty.	System	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'I'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:07:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

US3092112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

US3092112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

US3092112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	Marissa Cervenka (b) (4)	17 Mar 2021 17:18:03

US3092112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User entered '0'	System	17 Mar 2021 17:18:03

US3092112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31
User entered '0'	System	17 Mar 2021 17:18:03

US3092112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:43:31

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:22:25
User entered 'USA-US086-2021-mRNA-1273-P301000009'		24 Mar 2021 16:04:56

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Foot edema - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:39:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:39:59
Data point term sent to Coder	System	24 Mar 2021 00:38:46
User entered 'Bilateral Foot Edema'	Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '01 Feb 2021'	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	24 Mar 2021 00:38:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Mar 2021 00:38:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Mar 2021 00:38:35
User entered '06 Feb 2021'	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	24 Mar 2021 00:41:23
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 00:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 00:40:44
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 00:40:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:40:44
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 00:38:35
User entered empty.	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
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)	24 Mar 2021 00:41:23
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).		24 Mar 2021 00:41:23
User entered '1' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:41:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	24 Mar 2021 00:40:44
User entered '0'	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '01 Feb 2021' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:40:44
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '06 Feb 2021' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:40:44
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:40:44
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '0'	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 00:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 00:40:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:40:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 00:38:35
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 00:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 00:40:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:40:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 00:38:35
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered 'I'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Catina Adams (b) (4)	24 Mar 2021 00:38:57
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Catina Adams (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

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 02:22:25
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	24 Mar 2021 00:38:35
	(b) (4)	

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	24 Mar 2021 00:43:44
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Mar 2021 00:43:44
User entered 'SUBJECT REPORTED THAT SHE WAS HOSPITALIZED ON 1/FEB-6/FEB/2021 FOR BILATERAL FOOT EDEMA and BILATERAL FOOT PAIN.' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:43:44
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Mar 2021 00:40:44
User entered empty.	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 00:40:44

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 00:38:35

US3092112

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:07:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 00:40:44

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:07:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:44:47
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:57:34

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

Name of Medication

Audit	User	Time (GMT)
User closed query 'Please add dexamethasone and tegretol to con meds in EDC.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 14:21:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Query 'Please add dexamethasone and tegretol to con meds in EDC.' answered with 'UPDATED' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:38:20
User opened query 'Please add dexamethasone and tegretol to con meds in EDC.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 21:36:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:59:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:59:18
Data point term sent to Coder	System	17 Aug 2020 22:58:33
User entered 'LISINOPRIL'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'HYPERTENSION'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Per CDM: Please reconcile, and complete the data field with the updated dosage reported by subject.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:21:14
Query 'Per CDM: Please reconcile, and complete the data field with the updated dosage reported by subject.' answered with 'confirmed. reported by subject' (Site from DM).		27 Jan 2021 17:29:20
User opened query 'Per CDM: Please reconcile, and complete the data field with the updated dosage reported by subject.' (Site from DM).		25 Nov 2020 17:50:23
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for single component medication. Please review and either correct dosage or name of medication or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).		25 Nov 2020 17:50:23
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for single component medication. Please review and either correct dosage or name of medication or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'called patient and confirmed that is the dosage she is taking 11/23/20' (Site from DM).	destiny robinson (b) (4) (b) (4)	23 Nov 2020 20:05:23
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for single component medication. Please review and either correct dosage or name of medication or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:26:20
User entered '20/25'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:28:51
User entered 'mg (mg)'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'mcg' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:28:51
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'once daily (QD)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 10:04:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Marissa Cervenka (b) (4)	17 Aug 2020 22:59:26
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 22:59:16
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Aug 2020 22:59:16
User entered 'UN UNK 2016' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	17 Aug 2020 22:59:16
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	17 Aug 2020 22:58:33
	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 22:58:33
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 22:58:33

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 06:20:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 06:20:22
Data point term sent to Coder	System	17 Aug 2020 23:01:36
User entered 'VALIUM'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 23:00:45

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'TEMPORMANDIBULAR JOINT DYSFUNCTION'	(b) (4) Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered '10'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'mg (mg)'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'as needed (PRN)'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:00:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 23:00:58
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:00:45
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 10:04:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 23:01:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:00:45
User entered 'UN UNK 1985'	Marissa Cervenka (b) (4) (b) (4)	17 Aug 2020 23:00:45

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	17 Aug 2020 23:00:45
	(b) (4)	

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:00:45

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:00:45

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:00:45

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 08:19:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE, PRODUCTSYNONYM: LOMOTIL [ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:01:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:01:50
Data point term sent to Coder	System	17 Mar 2021 16:52:43
User entered '(LOMOTIL) DIPHENOXYLATE / ATROPINE' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:51:46
Data point term sent to Coder	System	17 Mar 2021 16:51:42
User entered '(LOMOTIN) DIPHENOXYLATE / ATROPINE' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:51:04
Data point term sent to Coder	System	17 Mar 2021 16:50:39
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:50:37
Coding entries removed.	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:50:29
User entered 'Diphenoxylate / Atropine' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:50:29

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:58:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: OTHER ANTIDIARRHEALS, ATC: OTHER ANTIDIARRHEALS, PRODUCT: ARECA CATECHU;ATRACTYLODES MACROCEPHALA, RHIZOMA;CITRUS RETICULATA;CODONOPSIS SPP.;ELEPHANTOPUS SCABER;HERBAL NOS;PAEDERIA FOETIDA;PLANTAGO LANCEOLATA;RAPHANUS SATIVUS;RHUS CHINENSIS;TALC, PRODUCTSYNONYM: ANTI DIARRHEA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:49:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:49:17
Data point term sent to Coder	System	23 Nov 2020 22:58:30
User entered 'ANTI- DIARRHEA'	(b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'DIARRHEA'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:53
User closed query 'Per DM CLR: Please review the combined dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. Otherwise, kindly confirm if the dose should be updated (i.e. 2.5/0.025) so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:13:02
Query 'Per DM CLR: Please review the combined dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. Otherwise, kindly confirm if the dose should be updated (i.e. 2.5/0.025) so there is an appropriate match. Update eCRF as appropriate.' answered with 'Update' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 13:38:24
User entered '2.5/0.025' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 13:38:15
User opened query 'Per DM CLR: Please review the combined dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. Otherwise, kindly confirm if the dose should be updated (i.e. 2.5/0.025) so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:13:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '2.5/25' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	17 Mar 2021 16:50:29
User entered '2'	(b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:13:10
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:39:29
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 13:39:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 13:39:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:12:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:53
Signature has been broken.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:39:21
User entered '17 Sep 2020' reason for change: Data Entry Error		06 Apr 2021 13:39:21
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 05:43:59
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated the correct answer according to source' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:30:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:29:43
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).		16 Dec 2020 06:27:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 22:57:59

PRODUCTION RELEASE (v12.003
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US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User entered empty.	System	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User entered empty.	System	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:19:55
User entered empty.	System	23 Nov 2020 22:57:59

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 20:19:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 20:19:48
Data point term sent to Coder Coding entries removed.	System Marissa Cervenka (b) (4)	17 Mar 2021 16:57:47 17 Mar 2021 16:57:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 23:04:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 23:04:04
Data point term sent to Coder User entered 'ALEVE'	System (b) (4), (b) (6)	23 Nov 2020 23:02:37 23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Per DM CLR: Note, there is no any correponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM). Query 'Per DM CLR: Note, there is no any correponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'DONE' (Site from DM). User entered 'LOW GRADE FEVER <100.4' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) Marissa Cervenka (b) (4) (b) (4) Marissa Cervenka (b) (4)	18 Mar 2021 08:18:56 17 Mar 2021 16:57:23 17 Mar 2021 16:57:15
User opened query 'Per DM CLR: Note, there is no any correponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM). User entered 'LOW GRADE FEVER'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 06:27:59 23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 08:18:59
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:57:30
User entered '220' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	17 Mar 2021 16:57:15
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 07:04:38
User entered '4'	(b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'mg (mg)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	17 Mar 2021 16:57:15
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:09:43
User entered 'once daily (QD)'		23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '18 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User entered empty.	System	24 Nov 2020 00:09:43
User entered '1'	System	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User entered empty.	System	24 Nov 2020 00:09:43
User entered '1'	System	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:06
User entered empty.	System	24 Nov 2020 00:09:43
User entered '804 (804)'	System	23 Nov 2020 23:01:42

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:40:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:40:15
Data point term sent to Coder	System	29 Mar 2021 23:17:32
Data point term sent to Coder	System	24 Mar 2021 00:28:44
Coding entries removed.	Catina Adams (b) (4) (b) (4)	24 Mar 2021 00:28:03
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Mar 2021 22:43:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:10:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:10:01
Data point term sent to Coder	System	05 Mar 2021 23:35:28
User entered 'DEXAMETHASONE'	(b) (4), (b) (6) (b) (4)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:53
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 23:17:28
User entered 'BILATERAL FOOT PAIN/ BILATERAL EDEMA/WORSENING OF BACK PAIN' reason for change: Data Entry Error		29 Mar 2021 23:17:28
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	(b) (4)	
	Catina Adams (b) (4)	24 Mar 2021 00:28:03
	(b) (4)	
User entered 'BILATERAL FOOT PAIN/ BILATERAL EDEMA' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:28:03
	(b) (4)	
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered 'CHRONIC BACK PAIN AND CHRONIC FOOT PAIN WITH EDEMA BILATERAL'	(b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '4'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
	(b) (4)	
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:24:34
	(b) (4)	
User entered '01 Feb 2021' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:24:34
	(b) (4)	
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
	(b) (4)	
User entered '20 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 23:35:01

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:58:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:58:37
Data point term sent to Coder	System	24 Mar 2021 00:21:34
Coding entries removed.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
Coding entries removed.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered 'Tramadol' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CARBAMAZEPINE, PRODUCTSYNONYM: TEGRETOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:50:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:50:07
Data point term sent to Coder	System	05 Mar 2021 23:38:29
User entered 'TEGRETOL'	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered 'Bilateral Foot Pain' reason for change:	Catina Adams (b) (4)	24 Mar 2021 00:21:19
Data Entry Error	(b) (4)	
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'CHRONIC BACK PAIN AND CHRONIC FOOT PAIN WITH BILATERAL EDEMA'	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered '50' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '120'	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered 'other (OTHER)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'four times daily (QID)'	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered 'Three Times a Day As Needed' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered '01 Feb 2021' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '20 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
Signature has been broken.	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User entered '06 Feb 2021' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 00:21:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User entered empty.	System	24 Mar 2021 00:21:19
User entered '4'	System	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User entered empty.	System	24 Mar 2021 00:21:19
User entered '1'	System	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:07:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:20:19
User entered empty.	System	24 Mar 2021 00:21:19
User entered '804 (804)'	System	05 Mar 2021 23:37:48

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:07:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:24
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:28:13
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Apr 2021 20:28:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	17 Mar 2021 17:32:45
Signature has been broken.	(b) (4) Marissa Cervenka (b) (4)	17 Mar 2021 17:32:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	17 Mar 2021 17:32:27
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:32:30

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:07:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:28:42

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:07:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Physical Therapy'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:28:42

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:07:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:28:42

US3092112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:07:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:28:42

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	20 Apr 2021 21:28:47
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4)	18 Mar 2021 16:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	System	18 Mar 2021 16:42:20
DataPoint Verified.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
Un-reviewed for Safety.	(b) (4)	02 Mar 2021 20:31:20
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:28:47
Un-reviewed for Safety.		20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
DataPoint Un-verified.	System	18 Mar 2021 16:42:20
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Un-reviewed for Safety.	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
User entered '25/Feb/2021 16:03'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:07:25

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)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'I'		25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	20 Apr 2021 21:28:47
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4)	18 Mar 2021 16:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	System	18 Mar 2021 16:42:20
DataPoint Verified.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
Un-reviewed for Safety.	(b) (4)	02 Mar 2021 20:31:20
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
User entered '25/Feb/2021 16:15'	System	25 Feb 2021 21:15:19

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 16:43:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
User entered 'I'		25 Feb 2021 21:15:19

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:28:47
Un-reviewed for Safety.		20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
DataPoint Un-verified.	System	18 Mar 2021 16:42:20
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Un-reviewed for Safety.	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
User entered '18/Mar/2021 12:42'	(b) (4) System	18 Mar 2021 16:42:57

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
User entered '1'		18 Mar 2021 16:42:57

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:28:47
Un-reviewed for Safety.		20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
DataPoint Un-verified.	System	18 Mar 2021 16:42:20
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Un-reviewed for Safety.	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User entered '24/Mar/2021 06:18'	(b) (4) System	24 Mar 2021 13:18:53

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
Reviewed for Safety.		07 Apr 2021 16:22:43
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:18:53

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:28:47
Un-reviewed for Safety.		20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
DataPoint Un-verified.	System	18 Mar 2021 16:42:20
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Un-reviewed for Safety.	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User entered '24/Mar/2021 09:05'	(b) (4) System	24 Mar 2021 16:05:36

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
Reviewed for Safety.		07 Apr 2021 16:22:43
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:05:36

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4)	20 Apr 2021 21:28:47
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4)	18 Mar 2021 16:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	System	18 Mar 2021 16:42:20
	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4)	02 Mar 2021 20:31:20
	(b) (4), (b) (6)	
Un-reviewed for Safety.		
	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User entered '25/Mar/2021 06:23'	(b) (4) System	25 Mar 2021 13:23:54

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
Reviewed for Safety.		07 Apr 2021 16:22:43
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:01:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:23:54

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:28:47
Un-reviewed for Safety.		20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
DataPoint Un-verified.	System	18 Mar 2021 16:42:20
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Un-reviewed for Safety.	Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:35:21
User entered '30/Mar/2021 06:49'	(b) (4) System	30 Mar 2021 13:49:29

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
Reviewed for Safety.		07 Apr 2021 16:22:43
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:35:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:49:29

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'USA-US086-2021-MRNA-1273-P301000009'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Yes (Y)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'No (N)'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Valentine'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Ebuh'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered '2701 S Hampton Road, Suite 250'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'Dallas'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:03:48
User entered 'TX'	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:28:47
Un-reviewed for Safety.		20 Apr 2021 21:28:17
Signature has been broken.		20 Apr 2021 21:28:17
User entered '75224' reason for change: Data Entry Error		20 Apr 2021 21:28:17
DataPoint Un-verified.		20 Apr 2021 20:44:53
DataPoint Verified.		06 Apr 2021 14:43:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:43:02
DataPoint Un-verified.	System	18 Mar 2021 16:42:20
Signature has been broken.	System	18 Mar 2021 16:42:20
User entered (b) (6)	System	18 Mar 2021 16:42:20
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Un-reviewed for Safety.	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	27 Feb 2021 22:10:06
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 21:03:48
User entered (b) (6) (non-conformant).	System	25 Feb 2021 21:02:49

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:23:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:20
Reviewed for Safety.		25 Feb 2021 21:15:13
User entered 'US'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:07:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	07 Apr 2021 16:22:54
User entered '7'	System	30 Mar 2021 13:49:29
User entered '6'	System	25 Mar 2021 13:23:54
User entered '5'	System	24 Mar 2021 16:05:36
User entered '4'	System	24 Mar 2021 13:18:53
User entered '3'	System	18 Mar 2021 16:42:57
User entered '2'	System	25 Feb 2021 21:15:19
User entered '1'	System	25 Feb 2021 21:03:59

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:07:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:53
User entered '07/Apr/2021 11:22'	(b) (4) System	07 Apr 2021 16:22:54

US3092112

Folder: SAE USA-US086-2021-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:07:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:38
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:22:54