

US3092043 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:05:26

All time stamps listed in this document are displayed in GMT

US3092043

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 00:28:08

Generated On: 09 Jun 2021 15:05:26

[Participant ID](#)

US3092043

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

US3092043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3092043

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3092043

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Date of Informed Consent (*dd MMM yyyy*) 6 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

US3092043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3092043

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Were any significant conditions reported?

Yes ☒

No ☐

US3092043

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	HEREDITARY HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3092043

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	MID SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3092043

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1954
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 1954
Start Year (derived)	1954
Stop Month and Year (derived)	
Stop Year (derived)	

US3092043

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3092043

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	16 JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3092043

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

US3092043

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN JAN 1998
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 JAN 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3092043

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1998
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 JAN 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3092043

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 14:59
Height (<i>xxx.x</i>)	166 cm
Weight (<i>xxx.x</i>)	82.7 kg
BMI (<i>xxx.x</i>)	30.01161 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)	

US3092043

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3092043

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Date of assessment (dd MMM yyyy) 06 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) UN JAN 1998

Date of surgery unknown False

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

Date of last menstruation unknown False

US3092043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3092043

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 184892

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 ☒

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Height	ND - Not Done
Weight	ND - Not Done

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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)	06 AUG 2020
Time of assessment (00:00-23:59)	14:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 14:59
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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)	06 AUG 2020
Time of assessment (00:00-23:59)	16:46 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:46
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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.

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 16:03 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 16:03

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

US3092043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 AUG 2020

Collection time (00:00-23:59)

15:40 (24 HR)

Collection date and time (derived)

6 AUG 2020 15:40

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	06 AUG 2020 15:35
Nasopharyngeal Swab 2	No		

US3092043

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 AUG 2020 16:44

PC Open Date & Time

06 AUG 2020 16:23

PC Close Date & Time

06 AUG 2020 18:53

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	06 AUG 2020 21:21
PC Open Date & Time	06 AUG 2020 19:48
PC Close Date & Time	07 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 16:23

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 14:40

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 15:34

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 16:20

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 15:14

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

06 AUG 2020 16:47

PC Open Date & Time

06 AUG 2020 16:23

PC Close Date & Time

06 AUG 2020 18:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 21:22

PC Open Date & Time

06 AUG 2020 19:48

PC Close Date & Time

07 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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

07 AUG 2020 16:23

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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

08 AUG 2020 14:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 15:34

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 16:20

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 15:14

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:48
PC Open Date & Time	06 AUG 2020 16:23
PC Close Date & Time	06 AUG 2020 18:53

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 21:23
PC Open Date & Time	06 AUG 2020 19:48
PC Close Date & Time	07 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 ☒

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 16:24
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 2365

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 14:42
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

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

56 of 2365

EAB) (1725)

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 15:35
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

58 of 2365

EAB) (1725)

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 16:21
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

60 of 2365

EAB) (1725)

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

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)

62 of 2365

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

Yes ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

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)	03 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

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)	03 SEP 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:00
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)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 12:30

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

US3092043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 SEP 2020

Collection time (00:00-23:59)

12:18 (24 HR)

Collection date and time (derived)

3 SEP 2020 12:18

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:18	03 SEP 2020 12:18
Nasopharyngeal Swab 2	No		

US3092043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

03 SEP 2020 13:16

PC Open Date & Time

03 SEP 2020 12:50

PC Close Date & Time

03 SEP 2020 15:20

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 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	03 SEP 2020 17:59
PC Open Date & Time	03 SEP 2020 16:15
PC Close Date & Time	04 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:58

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:20

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 17:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 15:50

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 15:40

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

03 SEP 2020 13:12

PC Open Date & Time

03 SEP 2020 12:50

PC Close Date & Time

03 SEP 2020 15:20

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 18:00

PC Open Date & Time

03 SEP 2020 16:15

PC Close Date & Time

04 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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

04 SEP 2020 16:58

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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

05 SEP 2020 19:46

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:19

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 17:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 15:50

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

09 SEP 2020 15:40

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 13:13
PC Open Date & Time	03 SEP 2020 12:50
PC Close Date & Time	03 SEP 2020 15:20

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:00
PC Open Date & Time	03 SEP 2020 16:15
PC Close Date & Time	04 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 ☒

PRODUCTION RELEASE (v12.003

98 of 2365

EAB) (1725)

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 16:59
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

100 of 2365

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

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)

102 of 2365

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:19
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 ☒

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:57
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 ☒

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 15:51
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 ☒

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 15:40
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3092043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 14:45
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3092043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	15:36 (24 HR)
Collection date and time (derived)	7 OCT 2020 15:36

US3092043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:10

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 16:29:38

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 09:19:24
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 09:04:19

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 11:22:23

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 21:04:28

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 00:02:36

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 00:34:52

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 09:15:55

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 17:00:15

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 20:56:02

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 00:03:43
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 09:48:08

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 01:13:49
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 23:30:31

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 00:02:06
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 20:31:14

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 12:01:06

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 00:01:50

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 00:08:48

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 15:40:11

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 12:33:54

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 10:41:53

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 01:29:15

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 01:10:52

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 01:54:59

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:02:09

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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°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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	27 OCT 2021 23:59
---	-------------------

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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="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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐
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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 530

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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="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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 642

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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="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"/>

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3092043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:05:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 12:00:38

US3092043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

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

Visit date (dd MMM yyyy)	23 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 16:32:19

Generated On: 09 Jun 2021 15:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:05
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 16:32:19

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3092043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 16:32:19

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 FEB 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	23 FEB 2021 13:40

US3092043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 16:32:19

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 16:32:19

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 14:04:40

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 14:04:40

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092043

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:05:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3092043

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3092043

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3092043

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Height	166.0 cm
Weight	197.8 lb
BMI (xxx.x)	32.62777

US3092043

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Height	166.0 cm
Weight	197.8 lb
BMI (xxx.x)	32.62777
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)	19 JAN 2021
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:20
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Height	166.0 cm
Weight	197.8 lb
BMI (xxx.x)	32.62777
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)	19 JAN 2021
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 15:19
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3092043

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 14:47 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 14:47

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

US3092043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

14:42 (24 HR)

Collection date and time (derived)

19 JAN 2021 14:42

US3092043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	14:39
Collection Date and Time (derived)	19 JAN 2021 14:39

US3092043

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments 1ST ATTEMPT ON 01/27/21/ NO
ANSWER

If Contact Not Made, please provide Comments 2ND ATTEMPT ON 01/28/21
CONTACT MADE

US3092043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

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)	23 FEB 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:05
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

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)	23 FEB 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:15
Temperature (xxx.x)	97.4 F
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3092043

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3092043

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 13:43 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 13:43

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

US3092043

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092043

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092043

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:15 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 13:15
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092043

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3092043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Mar 2021 00:59:56

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	24 MAR 2021 13:40

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

Visit Date	23 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 FEB 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	23 FEB 2021 13:40

US3092043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 00:28:08

Generated On: 09 Jun 2021 15:05:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

AEID	USA-US086-2020-MRNA-1273-P30 1000005
Adverse event	ASTHMA EXACERBATION
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)	2 OCT 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)	10 NOV 2020
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)	28 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	04 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2365

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

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	

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

SUBJECT REPORTED
HOSPITALIZATION FOR COPD
ASTHMA EXACERBATION.
SUBJECT WAS ADMITTED ON 28
OCTOBER 2020 AND
DISCHARGED 4 NOVEMBER
2020. MEDICAL RECORDS HAVE
BEEN REQUESTED.
ADDITIONAL INFORMATION
WILL BE PROVIDED UPON
RECEIVING MEDICAL
RECORDS.

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)	

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

AEID	USA-US086-2020-MRNA-1273-P30 1000005
Adverse event	CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION
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)	02 OCT 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)	10 NOV 2020
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)	28 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	04 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2365

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

	Unknown	<input type="radio"/>
<hr/>		
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"/>
<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)		
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 22:39:27

Generated On: 09 Jun 2021 15:05:26

VISIT DAY 57 THE SUBJECT
REPORTED EXACERBATION
WHICH STARTED ON 2 OCT
2020. AT DAY 85 PHONE CALL
THE SUBJECT INFORMED THE
SITE THAT SHE WAS
HOSPITALIZED FOR
EXACERBATION ON 28 OCT
2020.

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

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

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

Yes ☒

No ☐

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

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication PREDISONE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/COPD
EXACERBATION

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)

363 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	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)	2 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)		9 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication XOLAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify EVERY 2 WEEKS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/COPD

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 NOV 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 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication TESSALON PERLES

Prophylaxis Yes ☐
No ☒

Indication COUGH DUE TO ASTHMA/COPD
EXACERBATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/COPD
EXACERBATION

Dose per administration 20

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)

371 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	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)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication PROTONIX (PANTOPRAZOLE)

Prophylaxis Yes ☐
No ☒

Indication COUGH DUE TO EXACERBATED
EVENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication DALIRESP

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 500

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)

375 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	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 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication MID SEASONAL ALLERGIC
RHINITIS

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)

377 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	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 2019
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"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication HEPATITIS A & B

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS HEPATITIS A & B

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

381 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		1 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication SHINGLES VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS SHINGLES

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

383 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication TETANUS VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS TETANUS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN SURGERY

Dose per administration 10/325

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

PRN EVERY 6 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:22:00

Generated On: 09 Jun 2021 15:05:26

	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)		09 APR 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Mar 2021 18:18:39

Generated On: 09 Jun 2021 15:05:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3092043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:05:26

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

US3092043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:05:26

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 ☐

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

SAEID	USA-US086-2020-MRNA-1273-P301000005
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)	4

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

SAEID	USA-US086-2020-MRNA-1273-P301000005
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)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:30
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

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

SAEID	USA-US086-2020-MRNA-1273-P301000005
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)	4
Date of submission (Pre-filled from custom function)	22/NOV/2020 11:05
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

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

SAEID	USA-US086-2020-MRNA-1273-P301000005
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)	4
Date of submission (Pre-filled from custom function)	25/NOV/2020 15:25
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.	True

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 00:28:09

Generated On: 09 Jun 2021 15:05:26

SAEID	USA-US086-2020-MRNA-1273-P301000005
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)	4
Date of submission (Pre-filled from custom function)	11/FEB/2021 10:11
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

US3092043 (Prod: Global Medical Research - M3 Wake Research)

US3092043

Form: Participant Creation

Generated On: 09 Jun 2021 15:05:26

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'US3092043'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:24:15

US3092043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 20:31:50

US3092043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:24:16

US3092043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	06 Aug 2020 20:31:50

US3092043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'SCRN'	System	06 Aug 2020 20:31:50

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:24:17

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '69'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'YEARS'	System	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '69'	System	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Female (F)'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'I'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:23

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '6 Aug 2020'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Aug 2020'	System	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '2020'	System	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Amendment 1 (1)'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 20:32:42

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Vicki Martinez (b) (4)	06 Aug 2020 20:32:53
User entered 'Yes (Y)'	(b) (4)	
	Vicki Martinez (b) (4)	06 Aug 2020 20:32:42
	(b) (4)	

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	06 Aug 2020 20:32:53
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	06 Aug 2020 20:32:42
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:24:16

US3092043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'I'	System	06 Aug 2020 20:32:59

US3092043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 20:32:59

US3092043

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:05:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:17:22

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
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 08:45:00
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 01:18:47
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.	Coder Import (b) (4) (b) (4)	18 Aug 2020 16:58:13
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 16:58:13
Data point term sent to Coder	System	17 Aug 2020 18:19:05
User entered 'HEREDITARY HYPERTENSION'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 2000'	Shraddha Dubal (b) (4)	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 2000'	System	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '2000'	System	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:18:13

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 18:20:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 18:20:10
Data point term sent to Coder	System	17 Aug 2020 18:19:04
User entered 'COPD'	Shraddha Dubal (b) (4)	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN Dec 2019'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Dec 2019'	System	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '2019'	System	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:18:43

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
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 08:45:12
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 01:19:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchitis chronic, LLT: Chronic bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:21:14
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 18:21:14
Data point term sent to Coder	System	17 Aug 2020 18:20:06
User entered 'CHRONIC BRONCHITIS'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN Dec 2019'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Dec 2019'	System	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '2019'	System	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:19:21

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:27:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:27:22
Data point term sent to Coder	System	17 Aug 2020 18:20:08
User entered 'MID SEASONAL ALLERGIES'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 1995'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1995'	System	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1995'	System	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:20:00

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
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 08:45:32
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 01:19:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:22:16
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 18:22:16
Data point term sent to Coder	System	17 Aug 2020 18:21:10
User entered 'ASTHMA'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 1954'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1954'	System	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1954'	System	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:20:21

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 18:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 18:22:16
Data point term sent to Coder	System	17 Aug 2020 18:21:11
User entered 'INSOMNIA'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 1990'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1990'	System	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1990'	System	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:20:43

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
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 08:45:47
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 01:19:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:22:17
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 18:22:17
Data point term sent to Coder	System	17 Aug 2020 18:21:11
User entered 'EMPHYSEMA'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '16 Jul 2020'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jul 2020'	System	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '2020'	System	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered empty.	System	17 Aug 2020 18:21:10

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User closed query 'Per DM CLR: Please note that this is not reflected in the Pregnancy eCRF. Please review and reconcile eCRF pages as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:12
Query 'Per DM CLR: Please note that this is not reflected in the Pregnancy eCRF. Please review and reconcile eCRF pages as appropriate.' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:11:56
Query 'Per DM CLR: Please review and reflect if this pertains to Left, Right or Bilateral Tubal Ligation. Update Med History eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:20:16
User opened query 'Per DM CLR: Please note that this is not reflected in the Pregnancy eCRF. Please review and reconcile eCRF pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 01:20:07
User opened query 'Per DM CLR: Please review and reflect if this pertains to Left, Right or Bilateral Tubal Ligation. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 01:19:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:23:18
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 18:23:18
Data point term sent to Coder	System	17 Aug 2020 18:22:13
User entered 'TUBAL LIGATION'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 1977'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 1977'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1977'	System	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1977'	System	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1977'	System	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1977'	System	17 Aug 2020 18:21:38

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:17:53
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Updated with Uterine Fibroids' (Site from DM).	Catina Adams (b) (4) (b) (4)	24 Mar 2021 22:13:11
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 05:42:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:13:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:13:49
Data point term sent to Coder	System	18 Nov 2020 21:12:35
User entered 'Hysterectomy'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User closed query 'Per DM CLR: Please note, start/stop date of MH = UN JAN 1996. However, surgical sterilization date recorded in Childbearing ecrf is UN UNK 1977. Review and reconcile dates and procedures as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:53:10
Query 'Per DM CLR: Please note, start/stop date of MH = UN JAN 1996. However, surgical sterilization date recorded in Childbearing ecrf is UN UNK 1977. Review and reconcile dates and procedures as appropriate. Else, clarify. ' answered with 'Both forms updated to reflect surgical sterilization (hysterectomy) date of UN JAN 1998. Per MH in source, tubal ligation was performed UN UNK 1977. ' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 19:44:56
User entered 'UN Jan 1998' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 19:34:52
User opened query 'Per DM CLR: Please note, start/stop date of MH = UN JAN 1996. However, surgical sterilization date recorded in Childbearing ecrf is UN UNK 1977. Review and reconcile dates and procedures as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 03:25:33
User entered 'un Jan 1996'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN Jan 1998' reason for change: Data Entry Error	Heather Jimenez (b) (4)	04 Feb 2021 19:34:52
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	18 Nov 2020 21:12:55
User entered 'UN Jan 1996' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 21:12:55
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	18 Nov 2020 21:12:27
User entered 'un Jan 1995'	Marissa Cervenka (b) (4)	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1998'	System	04 Feb 2021 19:34:52
User entered 'Jan 1996'	System	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1998'	System	04 Feb 2021 19:34:52
User entered '1996'	System	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1998'	System	04 Feb 2021 19:34:52
User entered 'Jan 1996'	System	18 Nov 2020 21:12:55
User entered 'Jan 1995'	System	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1998'	System	04 Feb 2021 19:34:52
User entered '1996'	System	18 Nov 2020 21:12:55
User entered '1995'	System	18 Nov 2020 21:12:27

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 22:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 22:13:41
Data point term sent to Coder	System	24 Mar 2021 22:12:47
User entered 'Uterine Fibroids'	Catina Adams (b) (4) (b) (4)	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN UNK 1998' reason for change:	(b) (4)	
Data Entry Error	Catina Adams (b) (4)	24 Mar 2021 22:12:22
User entered 'UN Dec 1998'	(b) (4)	
	Catina Adams (b) (4)	24 Mar 2021 22:12:03
	(b) (4)	

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'No (N)'	Catina Adams (b) (4)	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	24 Mar 2021 22:12:22
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	24 Mar 2021 22:12:03
User entered 'UN Jan 1998'	Catina Adams (b) (4)	24 Mar 2021 22:12:03
	(b) (4)	

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Catina Adams (b) (4)	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1998'	System	24 Mar 2021 22:12:22
User entered 'Dec 1998'	System	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1998'	System	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'Jan 1998'	System	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '1998'	System	24 Mar 2021 22:12:03

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '06 Aug 2020'	Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:59'	Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered '06 Aug 2020 14:59'	System	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '166' cm	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09
DataPoint set to visible.	(b) (4) System	06 Aug 2020 20:32:59

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '82.7' kg	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09
DataPoint set to visible.	(b) (4) System	06 Aug 2020 20:32:59

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
Amendment Manager: User entered '30.01161'	System	16 Sep 2020 23:46:25
User entered '30.0'	System	17 Aug 2020 18:23:09
DataPoint set to visible.	System	06 Aug 2020 20:32:59

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'kg/m2'	System	17 Aug 2020 18:23:09
DataPoint set to visible.	System	06 Aug 2020 20:32:59

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:58:00
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	21 Oct 2020 02:07:56
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Oct 2020 02:07:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 02:07:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	21 Oct 2020 02:07:50
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:41:30
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 18:23:09
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:58:02
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Vicki Martinez (b) (4) (b) (4)	21 Oct 2020 02:08:01
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 18:23:09
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Oct 2020 02:07:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 02:07:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4)	21 Oct 2020 02:07:50
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 18:23:09
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'bpm'	System	21 Oct 2020 02:07:50
User entered empty.	System	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Oct 2020 02:07:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 02:07:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4)	21 Oct 2020 02:07:50
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 18:23:09
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'breaths/min'	System	21 Oct 2020 02:07:50
User entered empty.	System	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Oct 2020 02:07:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 02:07:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4)	21 Oct 2020 02:07:50
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 18:23:09
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'mmHg'	System	21 Oct 2020 02:07:50
User entered empty.	System	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Oct 2020 02:07:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 02:07:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4)	21 Oct 2020 02:07:50
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Aug 2020 18:23:09
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User entered 'mmHg'	System	21 Oct 2020 02:07:50
User entered empty.	System	17 Aug 2020 18:23:09

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21

US3092043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21

US3092043

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:23:24

US3092043

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:46:59
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 17:19:22
User entered '06 Aug 2020'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:23:24

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '06 Aug 2020'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'No (N)'	Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User closed query 'Per DM CLR: Note, 'If No, what is the reason?' = Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:18:23
Query 'Per DM CLR: Note, 'If No, what is the reason?' = Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'Uterine Fibroids updated.' (Site from DM).	Catina Adams (b) (4) (b) (4)	24 Mar 2021 22:14:41
User opened query 'Per DM CLR: Note, 'If No, what is the reason?' = Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:48:13
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 13:53:13
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 19:42:26

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

If No, what is the reason?

Audit	User	Time (GMT)
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'UPDATE MADE ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:13:16
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	28 Jan 2021 18:12:43
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	28 Jan 2021 18:12:13
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 18:12:13
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).		15 Dec 2020 08:01:34
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure (i.e. Hysterectomy) is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:21:35
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure (i.e. Hysterectomy) is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4)	18 Nov 2020 21:11:00

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		18 Nov 2020 21:10:02
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure (i.e. Hysterectomy) is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:41:46
User opened query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		17 Aug 2020 18:24:38
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty; reason for change Data Entry Error	Heather Jimenez (b) (4)	04 Feb 2021 19:42:26
User entered 'TUBAL LIGATION' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 18:12:13
User closed query 'Per CDM: Please record this procedure in Medical History form and confirm if "Hysterectomy" (1998) or "Tubal Ligation" (1977) is the primary reason for Non-Childbearing potential, as per page 24 of CCGs. Thank you.' (Site from DM).		19 Nov 2020 18:00:53
Query 'Per CDM: Please record this procedure in Medical History form and confirm if "Hysterectomy" (1998) or "Tubal Ligation" (1977) is the primary reason for Non-Childbearing potential, as per page 24 of CCGs. Thank you.' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4)	18 Nov 2020 21:11:05
User entered empty; reason for change Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 21:10:02
User opened query 'Per CDM: Please record this procedure in Medical History form and confirm if "Hysterectomy" (1998) or "Tubal Ligation" (1977) is the primary reason for Non-Childbearing potential, as per page 24 of CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:10:42
User entered 'HYSTERECTOMY'	Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'UN Jan 1998' reason for change: Data Entry Error	Heather Jimenez (b) (4)	04 Feb 2021 19:42:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 18:12:43
User entered 'UN UNK 1977' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 21:10:53
User entered 'UN Jan 1998'	Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:05:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '0'	Shraddha Dubal (b) (4)	17 Aug 2020 18:24:38

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Aug 2020 20:45:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 20:45:13
User entered 'No (N)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	06 Aug 2020 20:45:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Aug 2020 20:45:02
User entered empty.	System	06 Aug 2020 20:45:02
	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02
	(b) (4)	

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Aug 2020 20:45:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 20:45:13
User entered 'No (N)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	06 Aug 2020 20:45:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Aug 2020 20:45:02
User entered empty.	System	06 Aug 2020 20:45:02
	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02
	(b) (4)	

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

[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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Aug 2020 20:45:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 20:45:31
User entered 'No (N)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	06 Aug 2020 20:45:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Aug 2020 20:45:02
User entered empty.	System	06 Aug 2020 20:45:02
	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02
	(b) (4)	

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

[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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

[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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'I'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 20:45:02

US3092043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 21:10:50

US3092043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '6 Aug 2020'	Vicki Martinez (b) (4)	06 Aug 2020 21:10:50

US3092043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	06 Aug 2020 21:10:50

US3092043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'VISIT1'	System	06 Aug 2020 21:10:50

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:59:26

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:41:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:41:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 20:59:26
User entered '184892' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:59:26

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:59:26

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

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)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:10

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

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)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:10

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:10

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:10

US3092043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:10

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 05:35:35
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:23
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:41:58
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 03:59:23
User entered empty.	Vicki Martinez (b) (4)	17 Aug 2020 18:28:28
	(b) (4)	

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 05:35:35
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:23
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:41:58
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 03:59:23
User entered empty.	Vicki Martinez (b) (4)	17 Aug 2020 18:28:28
	(b) (4)	

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Pre-Dose (PREDOSE)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '06 Aug 2020'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:59'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '06 Aug 2020 14:59'	System	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '36.9' C	Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (Oral)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '88'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'bpm'	System	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'breaths/min'	System	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '135'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '86'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 05:35:35
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:23
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on V1D1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:41:58
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:28:28

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 03:59:23
User entered empty.	Vicki Martinez (b) (4)	23 Oct 2020 03:59:23
	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:28:28
	(b) (4)	

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Post-Dose (POSTDOSE)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '06 Aug 2020'	Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 02:41:41
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 18:30:06
User entered '16:46'	Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06
	(b) (4)	

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '06 Aug 2020 16:46'	System	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '97.9' F	Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (Oral)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '88'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'bpm'	System	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '16'	Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'breaths/min'	System	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '138'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '80'	Shraddha Dubal (b) (4)	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	17 Aug 2020 18:30:06

US3092043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:30:18

US3092043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:30:18

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '6 Aug 2020'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '16:03'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '6 Aug 2020 16:03'	System	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Left Arm (LEFT ARM)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'ONCE'	System	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 21:11:28

US3092043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 18:23:30

US3092043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	03 Sep 2020 18:25:12
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	03 Sep 2020 18:25:12
User entered '6 Aug 2020' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:25:12
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	03 Sep 2020 18:23:30
User entered '3 Sep 2020'	System	03 Sep 2020 18:23:30
	Vicki Martinez (b) (4)	03 Sep 2020 18:23:30
	(b) (4)	

US3092043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '15:40' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:25:12
User entered '12:25'	Vicki Martinez (b) (4)	03 Sep 2020 18:23:30

US3092043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '6 Aug 2020 15:40'	System	03 Sep 2020 18:25:12
User entered '3 Sep 2020 12:25'	System	03 Sep 2020 18:23:30

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '06 Aug 2020'	Vicki Martinez (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Vicki Martinez (b) (4) (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '15:35'	Vicki Martinez (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '06 Aug 2020 15:35'	System	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Vicki Martinez (b) (4) (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered empty.	System	03 Sep 2020 18:26:01

US3092043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 21:11:35

US3092043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	06 Aug 2020 21:11:35

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:29:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '62f86d35-93a1-4452-b7ee-32bdda6dcac5'	System	06 Aug 2020 21:44:50
User entered 'Yes (Y)'	System	06 Aug 2020 21:44:50

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:44:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '62f86d35-93a1-4452-b7ee-32bdda6dcac5'	System	06 Aug 2020 21:44:50
User entered '97.9'	System	06 Aug 2020 21:44:50

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:44:35', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '62f86d35-93a1-4452-b7ee-32bdda6dcac5'	System	06 Aug 2020 21:44:50
User entered 'No (N)'	System	06 Aug 2020 21:44:50

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:44:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '62f86d35-93a1-4452-b7ee-32bdda6dcac5'	System	06 Aug 2020 21:44:50
User entered '06 Aug 2020 16:44'	System	06 Aug 2020 21:44:50

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 16:23'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 18:53'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:20:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7381c141-b82c-4fa7-bcb2-79774bd79306'	System	07 Aug 2020 02:21:24
User entered 'Yes (Y)'	System	07 Aug 2020 02:21:24

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7381c141-b82c-4fa7-bcb2-79774bd79306'	System	07 Aug 2020 02:21:24
User entered '98.2'	System	07 Aug 2020 02:21:24

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:08', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7381c141-b82c-4fa7-bcb2-79774bd79306'	System	07 Aug 2020 02:21:24
User entered 'No (N)'	System	07 Aug 2020 02:21:24

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7381c141-b82c-4fa7-bcb2-79774bd79306'	System	07 Aug 2020 02:21:24
User entered '06 Aug 2020 21:21'	System	07 Aug 2020 02:21:24

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 19:48'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 2'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:22:37', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2b42bd5f-b356-49e9-aacc-0b204f6f320f'	System	07 Aug 2020 21:23:06
User entered 'Yes (Y)'	System	07 Aug 2020 21:23:06

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:22:45', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2b42bd5f-b356-49e9-aacc-0b204f6f320f' User entered '98.3'	System	07 Aug 2020 21:23:06
	System	07 Aug 2020 21:23:06

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:22:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2b42bd5f-b356-49e9-aacc-0b204f6f320f'	System	07 Aug 2020 21:23:06
User entered 'No (N)'	System	07 Aug 2020 21:23:06

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2b42bd5f-b356-49e9-aacc-0b204f6f320f'	System	07 Aug 2020 21:23:06
User entered '07 Aug 2020 16:23'	System	07 Aug 2020 21:23:06

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 3'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:39:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f5a68591-b43d-48b4-bb70-3c27e0585cd7'	System	08 Aug 2020 19:40:56
User entered 'Yes (Y)'	System	08 Aug 2020 19:40:56

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:40:35', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f5a68591-b43d-48b4-bb70-3c27e0585cd7'	System	08 Aug 2020 19:40:56
User entered '98.2'	System	08 Aug 2020 19:40:56

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:40:40', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f5a68591-b43d-48b4-bb70-3c27e0585cd7'	System	08 Aug 2020 19:40:56
User entered 'No (N)'	System	08 Aug 2020 19:40:56

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:40:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f5a68591-b43d-48b4-bb70-3c27e0585cd7'	System	08 Aug 2020 19:40:56
User entered '08 Aug 2020 14:40'	System	08 Aug 2020 19:40:56

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 4'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:33:54', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c620fba7-41f3-4237-9478-a5f23af3f458'	System	09 Aug 2020 20:34:16
User entered 'Yes (Y)'	System	09 Aug 2020 20:34:16

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c620fba7-41f3-4237-9478-a5f23af3f458'	System	09 Aug 2020 20:34:16
User entered '99.2'	System	09 Aug 2020 20:34:16

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c620fba7-41f3-4237-9478-a5f23af3f458'	System	09 Aug 2020 20:34:16
User entered 'No (N)'	System	09 Aug 2020 20:34:16

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:13', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c620fba7-41f3-4237-9478-a5f23af3f458'	System	09 Aug 2020 20:34:16
User entered '09 Aug 2020 15:34'	System	09 Aug 2020 20:34:16

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 5'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:19:54', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '957d2d26-4934-4531-9508-d4352194fdae'	System	10 Aug 2020 21:20:20
User entered 'Yes (Y)'	System	10 Aug 2020 21:20:20

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '957d2d26-4934-4531-9508-d4352194fdae' User entered '98.1'	System	10 Aug 2020 21:20:20
	System	10 Aug 2020 21:20:20

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '957d2d26-4934-4531-9508-d4352194fdae'	System	10 Aug 2020 21:20:20
User entered 'No (N)'	System	10 Aug 2020 21:20:20

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '957d2d26-4934-4531-9508-d4352194fdae'	System	10 Aug 2020 21:20:20
User entered '10 Aug 2020 16:20'	System	10 Aug 2020 21:20:20

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 6'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:13:40', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9ebf3022-4820-405f-ab2d-5d071fc1c997'	System	11 Aug 2020 20:14:05
User entered 'Yes (Y)'	System	11 Aug 2020 20:14:05

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:13:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9ebf3022-4820-405f-ab2d-5d071fc1c997'	System	11 Aug 2020 20:14:05
User entered '99.1'	System	11 Aug 2020 20:14:05

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:13:54', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9ebf3022-4820-405f-ab2d-5d071fc1c997'	System	11 Aug 2020 20:14:05
User entered 'No (N)'	System	11 Aug 2020 20:14:05

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9ebf3022-4820-405f-ab2d-5d071fc1c997'	System	11 Aug 2020 20:14:05
User entered '11 Aug 2020 15:14'	System	11 Aug 2020 20:14:05

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 7'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:45:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e21c95a1-459f-4a86-9128-da4c8f4c750d'	System	06 Aug 2020 21:47:53
User entered 'None (1)'	System	06 Aug 2020 21:47:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:45:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e21c95a1-459f-4a86-9128-da4c8f4c750d'	System	06 Aug 2020 21:47:53
User entered 'No (N)'	System	06 Aug 2020 21:47:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:45:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e21c95a1-459f-4a86-9128-da4c8f4c750d'	System	06 Aug 2020 21:47:53
User entered 'Yes (Y)'	System	06 Aug 2020 21:47:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:47:30', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e21c95a1-459f-4a86-9128-da4c8f4c750d'	System	06 Aug 2020 21:47:53
User entered '3'	System	06 Aug 2020 21:47:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:47:39', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e21c95a1-459f-4a86-9128-da4c8f4c750d'	System	06 Aug 2020 21:47:53
User entered 'None (1)'	System	06 Aug 2020 21:47:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:47:49', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e21c95a1-459f-4a86-9128-da4c8f4c750d'	System	06 Aug 2020 21:47:53
User entered '06 Aug 2020 16:47'	System	06 Aug 2020 21:47:53

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 16:23'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 18:53'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:32', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '833f1c9d-4084-45c0-b1dd-ae71b209f0b5'	System	07 Aug 2020 02:22:08
User entered 'None (1)'	System	07 Aug 2020 02:22:08

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '833f1c9d-4084-45c0-b1dd-ae71b209f0b5'	System	07 Aug 2020 02:22:08
User entered 'No (N)'	System	07 Aug 2020 02:22:08

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '833f1c9d-4084-45c0-b1dd-ae71b209f0b5'	System	07 Aug 2020 02:22:08
User entered 'No (N)'	System	07 Aug 2020 02:22:08

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:21:59', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '833f1c9d-4084-45c0-b1dd-ae71b209f0b5'	System	07 Aug 2020 02:22:08
User entered 'None (1)'	System	07 Aug 2020 02:22:08

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '833f1c9d-4084-45c0-b1dd-ae71b209f0b5'	System	07 Aug 2020 02:22:08
User entered '06 Aug 2020 21:22'	System	07 Aug 2020 02:22:08

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 19:48'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 2'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:10', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7d1b50ba-e123-4858-a2aa-a2e3bb54b4e1'	System	07 Aug 2020 21:23:43
User entered 'None (1)'	System	07 Aug 2020 21:23:43

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:16', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7d1b50ba-e123-4858-a2aa-a2e3bb54b4e1'	System	07 Aug 2020 21:23:43
User entered 'No (N)'	System	07 Aug 2020 21:23:43

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:20', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7d1b50ba-e123-4858-a2aa-a2e3bb54b4e1'	System	07 Aug 2020 21:23:43
User entered 'No (N)'	System	07 Aug 2020 21:23:43

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:23', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7d1b50ba-e123-4858-a2aa-a2e3bb54b4e1'	System	07 Aug 2020 21:23:43
User entered 'None (1)'	System	07 Aug 2020 21:23:43

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:36', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7d1b50ba-e123-4858-a2aa-a2e3bb54b4e1'	System	07 Aug 2020 21:23:43
User entered '07 Aug 2020 16:23'	System	07 Aug 2020 21:23:43

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 3'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c360d4a4-b961-401c-88c2-7b47c1c695a0'	System	08 Aug 2020 19:41:26
User entered 'None (1)'	System	08 Aug 2020 19:41:26

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c360d4a4-b961-401c-88c2-7b47c1c695a0'	System	08 Aug 2020 19:41:26
User entered 'No (N)'	System	08 Aug 2020 19:41:26

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c360d4a4-b961-401c-88c2-7b47c1c695a0'	System	08 Aug 2020 19:41:26
User entered 'No (N)'	System	08 Aug 2020 19:41:26

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:19', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c360d4a4-b961-401c-88c2-7b47c1c695a0'	System	08 Aug 2020 19:41:26
User entered 'None (1)'	System	08 Aug 2020 19:41:26

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c360d4a4-b961-401c-88c2-7b47c1c695a0'	System	08 Aug 2020 19:41:26
User entered '08 Aug 2020 14:41'	System	08 Aug 2020 19:41:26

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 4'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:18', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b69308c4-12ca-4164-8721-d9f51089b32c'	System	09 Aug 2020 20:34:37
User entered 'None (1)'	System	09 Aug 2020 20:34:37

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b69308c4-12ca-4164-8721-d9f51089b32c'	System	09 Aug 2020 20:34:37
User entered 'No (N)'	System	09 Aug 2020 20:34:37

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:25', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b69308c4-12ca-4164-8721-d9f51089b32c'	System	09 Aug 2020 20:34:37
User entered 'No (N)'	System	09 Aug 2020 20:34:37

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:29', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b69308c4-12ca-4164-8721-d9f51089b32c'	System	09 Aug 2020 20:34:37
User entered 'None (1)'	System	09 Aug 2020 20:34:37

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b69308c4-12ca-4164-8721-d9f51089b32c'	System	09 Aug 2020 20:34:37
User entered '09 Aug 2020 15:34'	System	09 Aug 2020 20:34:37

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 5'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b3d2a887-4bb3-4fc1-99d3-d46c35d1ba51'	System	10 Aug 2020 21:20:47
User entered 'None (1)'	System	10 Aug 2020 21:20:47

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:32', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b3d2a887-4bb3-4fc1-99d3-d46c35d1ba51'	System	10 Aug 2020 21:20:47
User entered 'No (N)'	System	10 Aug 2020 21:20:47

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:34', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b3d2a887-4bb3-4fc1-99d3-d46c35d1ba51'	System	10 Aug 2020 21:20:47
User entered 'No (N)'	System	10 Aug 2020 21:20:47

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:37', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b3d2a887-4bb3-4fc1-99d3-d46c35d1ba51'	System	10 Aug 2020 21:20:47
User entered 'None (1)'	System	10 Aug 2020 21:20:47

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b3d2a887-4bb3-4fc1-99d3-d46c35d1ba51'	System	10 Aug 2020 21:20:47
User entered '10 Aug 2020 16:20'	System	10 Aug 2020 21:20:47

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 6'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44d51f91-b7e9-4c6f-b16e-6a717852d3a0'	System	11 Aug 2020 20:14:27
User entered 'None (1)'	System	11 Aug 2020 20:14:27

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:10', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44d51f91-b7e9-4c6f-b16e-6a717852d3a0'	System	11 Aug 2020 20:14:27
User entered 'No (N)'	System	11 Aug 2020 20:14:27

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44d51f91-b7e9-4c6f-b16e-6a717852d3a0'	System	11 Aug 2020 20:14:27
User entered 'No (N)'	System	11 Aug 2020 20:14:27

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:14', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44d51f91-b7e9-4c6f-b16e-6a717852d3a0'	System	11 Aug 2020 20:14:27
User entered 'None (1)'	System	11 Aug 2020 20:14:27

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44d51f91-b7e9-4c6f-b16e-6a717852d3a0'	System	11 Aug 2020 20:14:27
User entered '11 Aug 2020 15:14'	System	11 Aug 2020 20:14:27

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 7'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:47:57', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'None (0)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'None (0)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'None (0)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:11', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'None (0)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'None (0)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:19', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'None (0)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:25', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered 'No (N)'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T16:48:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c194d9ef-7880-40fb-b133-95c7337baa47'	System	06 Aug 2020 21:48:55
User entered '06 Aug 2020 16:48'	System	06 Aug 2020 21:48:55

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 16:23'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 18:53'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'None (0)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:29', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'No interference with activity (1)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:35', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'None (0)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:40', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'None (0)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:42', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'None (0)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'None (0)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:22:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered 'No (N)'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-06T21:23:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'bde4ef1d-484d-41b1-9ba5-9c8c41bba85e'	System	07 Aug 2020 02:23:03
User entered '06 Aug 2020 21:23'	System	07 Aug 2020 02:23:03

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Aug 2020 19:48'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 2'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:45', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'None (0)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:53', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'None (0)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:23:57', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'None (0)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:24:03', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'None (0)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:24:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'None (0)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:24:09', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'None (0)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:24:13', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered 'No (N)'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-07T16:24:20', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ac2e6d15-7598-4c43-8c4e-f0fbbda85c67'	System	07 Aug 2020 21:24:23
User entered '07 Aug 2020 16:24'	System	07 Aug 2020 21:24:23

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 3'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:29', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'None (0)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'None (0)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:37', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'None (0)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:40', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'None (0)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'None (0)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:47', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'None (0)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:41:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered 'No (N)'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-08T14:42:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '483d83d2-041e-4cc7-a36d-caf73fbed6c4'	System	08 Aug 2020 19:42:06
User entered '08 Aug 2020 14:42'	System	08 Aug 2020 19:42:06

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 4'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:40', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'None (0)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:45', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'None (0)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:49', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'None (0)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'None (0)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:34:56', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'None (0)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:35:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'None (0)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:35:03', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered 'No (N)'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-09T15:35:13', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '992db730-0e90-4af2-9b41-5fdff19d3fa6'	System	09 Aug 2020 20:35:15
User entered '09 Aug 2020 15:35'	System	09 Aug 2020 20:35:15

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 5'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:48', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'None (0)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'None (0)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'None (0)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:20:58', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'None (0)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:21:01', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'None (0)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:21:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'None (0)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:21:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered 'No (N)'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-10T16:21:14', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'df3f7093-482b-40fd-91ab-af21116e872e'	System	10 Aug 2020 21:21:19
User entered '10 Aug 2020 16:21'	System	10 Aug 2020 21:21:19

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 6'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'None (0)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'None (0)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:36', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'None (0)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:39', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'None (0)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'None (0)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'None (0)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered 'No (N)'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-08-11T15:14:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ba0cc20b-768f-49d8-a3ab-d82eb6a0cd2e'	System	11 Aug 2020 20:14:58
User entered '11 Aug 2020 15:14'	System	11 Aug 2020 20:14:58

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 7'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:11:28

US3092043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	15 Aug 2020 20:38:55

US3092043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '15 Aug 2020'	Catina Adams (b) (4)	15 Aug 2020 20:38:55

US3092043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	15 Aug 2020 20:38:55

US3092043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Catina Adams (b) (4)	15 Aug 2020 20:38:55

US3092043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	15 Aug 2020 20:39:05

US3092043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	15 Aug 2020 20:39:05

US3092043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Sep 2020 16:49:26

US3092043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '20 Aug 2020'	Catina Adams (b) (4)	01 Sep 2020 16:49:26

US3092043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	01 Sep 2020 16:49:26

US3092043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Catina Adams (b) (4)	01 Sep 2020 16:49:26

US3092043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Sep 2020 16:50:22

US3092043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	01 Sep 2020 16:50:22

US3092043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Sep 2020 16:51:54

US3092043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '28 Aug 2020'	Catina Adams (b) (4)	01 Sep 2020 16:51:54

US3092043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	01 Sep 2020 16:51:54

US3092043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Catina Adams (b) (4)	01 Sep 2020 16:51:54

US3092043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Sep 2020 16:52:02

US3092043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	01 Sep 2020 16:52:02

US3092043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:19:22

US3092043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '03 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:19:22

US3092043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	03 Sep 2020 17:19:22

US3092043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'VISIT2'	System	03 Sep 2020 17:19:22

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Pre-Dose (PREDOSE)'	Vicki Martinez (b) (4) (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '03 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12:00'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '03 Sep 2020 12:00'	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query "Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).	(b) (4)	07 Oct 2020 13:05:33
Query "Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." answered by data change (Site from System).	System	07 Oct 2020 13:05:33
User entered '98.1' F reason for change: Data Entry Error	Catina Adams (b) (4)	07 Oct 2020 13:05:33
Amendment Manager: User opened query "Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).	(b) (4)	16 Sep 2020 23:46:25
User entered '98.1' C	System	16 Sep 2020 23:46:25
	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (Oral)'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '88'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'bpm'	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'breaths/min'	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '113'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '74'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Post-Dose (POSTDOSE)'	Vicki Martinez (b) (4) (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '03 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 18:27:08
User entered '13:00' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:27:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 17:25:58
User entered empty.	System	03 Sep 2020 17:25:58
	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '03 Sep 2020 13:00'	System	03 Sep 2020 18:27:08
User entered empty.	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 18:27:08
User entered '98.6' F reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:27:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 17:25:58
User entered empty.	System	03 Sep 2020 17:25:58
	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 18:27:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:27:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
User entered empty.	System	03 Sep 2020 17:25:58
	Vicki Martinez (b) (4)	
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 18:27:08
User entered '93' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:27:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 17:25:58
User entered empty.	System	03 Sep 2020 17:25:58
	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'bpm'	System	03 Sep 2020 18:27:08
User entered empty.	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
Query 'Data is required. Please provide.' answered by System	System	03 Sep 2020 18:27:08
data change (Site from System).		03 Sep 2020 18:27:08
User entered '15' reason for change: Data Entry	Vicki Martinez (b) (4)	03 Sep 2020 18:27:08
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 17:25:58
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'breaths/min'	System	03 Sep 2020 18:27:08
User entered empty.	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 18:27:08
User entered '131' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:27:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 17:25:58
User entered empty.	System	03 Sep 2020 17:25:58
	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	03 Sep 2020 18:27:08
User entered empty.	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 18:27:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 18:27:08
User entered '88' reason for change: Data Entry Error	Vicki Martinez (b) (4)	03 Sep 2020 18:27:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 17:25:58
User entered empty.	System	03 Sep 2020 17:25:58
	Vicki Martinez (b) (4)	03 Sep 2020 17:25:58
	(b) (4)	

US3092043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	03 Sep 2020 18:27:08
User entered empty.	System	03 Sep 2020 17:25:58

US3092043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:26:09

US3092043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '03 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:26:09

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '03 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12:30'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '03 Sep 2020 12:30'	System	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Left Arm (LEFT ARM)'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'ONCE'	System	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 17:43:41

US3092043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:42:52

US3092043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '3 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:42:52

US3092043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12:18'	Vicki Martinez (b) (4)	03 Sep 2020 17:42:52

US3092043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '3 Sep 2020 12:18'	System	03 Sep 2020 17:42:52

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '03 Sep 2020'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Vicki Martinez (b) (4) (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12:18'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '03 Sep 2020 12:18'	System	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Vicki Martinez (b) (4) (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Vicki Martinez (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Vicki Martinez (b) (4)	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered empty.	System	03 Sep 2020 17:43:11

US3092043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	03 Sep 2020 17:26:56

US3092043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	03 Sep 2020 17:26:56

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:15:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b6d3e550-8909-4602-930f-3ba06bd5c3ca'	System	03 Sep 2020 18:16:19
User entered 'Yes (Y)'	System	03 Sep 2020 18:16:19

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:16:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b6d3e550-8909-4602-930f-3ba06bd5c3ca'	System	03 Sep 2020 18:16:19
User entered '98.6'	System	03 Sep 2020 18:16:19

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:16:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b6d3e550-8909-4602-930f-3ba06bd5c3ca'	System	03 Sep 2020 18:16:19
User entered 'No (N)'	System	03 Sep 2020 18:16:19

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:16:14', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b6d3e550-8909-4602-930f-3ba06bd5c3ca'	System	03 Sep 2020 18:16:19
User entered '03 Sep 2020 13:16'	System	03 Sep 2020 18:16:19

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 12:50'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 15:20'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T17:59:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '948c72d9-aa46-433e-9377-5bdc4f9d6992'	System	03 Sep 2020 22:59:59
User entered 'Yes (Y)'	System	03 Sep 2020 22:59:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T17:59:39', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '948c72d9-aa46-433e-9377-5bdc4f9d6992'	System	03 Sep 2020 22:59:59
User entered '97.8'	System	03 Sep 2020 22:59:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T17:59:43', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '948c72d9-aa46-433e-9377-5bdc4f9d6992'	System	03 Sep 2020 22:59:59
User entered 'No (N)'	System	03 Sep 2020 22:59:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T17:59:53', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '948c72d9-aa46-433e-9377-5bdc4f9d6992'	System	03 Sep 2020 22:59:59
User entered '03 Sep 2020 17:59'	System	03 Sep 2020 22:59:59

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 16:15'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 2'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:57:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c328c657-cece-46b7-9dd3-5c7f571a858f'	System	04 Sep 2020 21:58:16
User entered 'Yes (Y)'	System	04 Sep 2020 21:58:16

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:03', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c328c657-cece-46b7-9dd3-5c7f571a858f' User entered '98.3'	System	04 Sep 2020 21:58:16
	System	04 Sep 2020 21:58:16

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c328c657-cece-46b7-9dd3-5c7f571a858f'	System	04 Sep 2020 21:58:16
User entered 'No (N)'	System	04 Sep 2020 21:58:16

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c328c657-cece-46b7-9dd3-5c7f571a858f'	System	04 Sep 2020 21:58:16
User entered '04 Sep 2020 16:58'	System	04 Sep 2020 21:58:16

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 3'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:47:47', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a521ed98-847a-46b5-a91b-f9228526e0fe'	System	06 Sep 2020 00:48:08
User entered 'Yes (Y)'	System	06 Sep 2020 00:48:08

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:47:53', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a521ed98-847a-46b5-a91b-f9228526e0fe'	System	06 Sep 2020 00:48:08
User entered '98.6'	System	06 Sep 2020 00:48:08

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:47:58', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a521ed98-847a-46b5-a91b-f9228526e0fe'	System	06 Sep 2020 00:48:08
User entered 'No (N)'	System	06 Sep 2020 00:48:08

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:48:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a521ed98-847a-46b5-a91b-f9228526e0fe'	System	06 Sep 2020 00:48:08
User entered '05 Sep 2020 19:48'	System	06 Sep 2020 00:48:08

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 4'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:20:01', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '345c3233-cd2a-4b76-9472-e6af17aa1057'	System	06 Sep 2020 23:20:25
User entered 'Yes (Y)'	System	06 Sep 2020 23:20:25

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:20:09', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '345c3233-cd2a-4b76-9472-e6af17aa1057'	System	06 Sep 2020 23:20:25
User entered '98.7'	System	06 Sep 2020 23:20:25

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:20:13', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '345c3233-cd2a-4b76-9472-e6af17aa1057'	System	06 Sep 2020 23:20:25
User entered 'No (N)'	System	06 Sep 2020 23:20:25

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:20:19', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '345c3233-cd2a-4b76-9472-e6af17aa1057'	System	06 Sep 2020 23:20:25
User entered '06 Sep 2020 18:20'	System	06 Sep 2020 23:20:25

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 5'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:24', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c222a7b4-0a1c-4bad-b115-2f9c2908a257'	System	07 Sep 2020 22:56:40
User entered 'Yes (Y)'	System	07 Sep 2020 22:56:40

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:30', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c222a7b4-0a1c-4bad-b115-2f9c2908a257'	System	07 Sep 2020 22:56:40
User entered '98.1'	System	07 Sep 2020 22:56:40

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c222a7b4-0a1c-4bad-b115-2f9c2908a257'	System	07 Sep 2020 22:56:40
User entered 'No (N)'	System	07 Sep 2020 22:56:40

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:37', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'c222a7b4-0a1c-4bad-b115-2f9c2908a257'	System	07 Sep 2020 22:56:40
User entered '07 Sep 2020 17:56'	System	07 Sep 2020 22:56:40

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 6'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:20', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'dac162a3-2b3e-41b2-80bd-f9da21919550'	System	08 Sep 2020 20:50:39
User entered 'Yes (Y)'	System	08 Sep 2020 20:50:39

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:27', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'dac162a3-2b3e-41b2-80bd-f9da21919550'	System	08 Sep 2020 20:50:39
User entered '97.7'	System	08 Sep 2020 20:50:39

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:32', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'dac162a3-2b3e-41b2-80bd-f9da21919550'	System	08 Sep 2020 20:50:39
User entered 'No (N)'	System	08 Sep 2020 20:50:39

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:36', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'dac162a3-2b3e-41b2-80bd-f9da21919550'	System	08 Sep 2020 20:50:39
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 20:50:39

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 7'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:39:48', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6de7d2ef-6416-4dac-8eb6-abd99ea20371'	System	09 Sep 2020 20:40:18
User entered 'Yes (Y)'	System	09 Sep 2020 20:40:18

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6de7d2ef-6416-4dac-8eb6-abd99ea20371' User entered '97.2'	System	09 Sep 2020 20:40:18
	System	09 Sep 2020 20:40:18

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:10', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6de7d2ef-6416-4dac-8eb6-abd99ea20371'	System	09 Sep 2020 20:40:18
User entered 'No (N)'	System	09 Sep 2020 20:40:18

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:13', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6de7d2ef-6416-4dac-8eb6-abd99ea20371'	System	09 Sep 2020 20:40:18
User entered '09 Sep 2020 15:40'	System	09 Sep 2020 20:40:18

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:11:56', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8ce21c95-69ad-4fa5-9e57-9ce513e0221d'	System	03 Sep 2020 18:12:45
User entered 'None (1)'	System	03 Sep 2020 18:12:45

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:12:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8ce21c95-69ad-4fa5-9e57-9ce513e0221d'	System	03 Sep 2020 18:12:45
User entered 'No (N)'	System	03 Sep 2020 18:12:45

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:12:26', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8ce21c95-69ad-4fa5-9e57-9ce513e0221d'	System	03 Sep 2020 18:12:45
User entered 'No (N)'	System	03 Sep 2020 18:12:45

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:12:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8ce21c95-69ad-4fa5-9e57-9ce513e0221d'	System	03 Sep 2020 18:12:45
User entered 'None (1)'	System	03 Sep 2020 18:12:45

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:12:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8ce21c95-69ad-4fa5-9e57-9ce513e0221d'	System	03 Sep 2020 18:12:45
User entered '03 Sep 2020 13:12'	System	03 Sep 2020 18:12:45

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 12:50'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 15:20'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f0320e17-8524-4c1e-ba01-81277345396d'	System	03 Sep 2020 23:00:37
User entered 'None (1)'	System	03 Sep 2020 23:00:37

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:17', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f0320e17-8524-4c1e-ba01-81277345396d'	System	03 Sep 2020 23:00:37
User entered 'No (N)'	System	03 Sep 2020 23:00:37

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:21', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f0320e17-8524-4c1e-ba01-81277345396d'	System	03 Sep 2020 23:00:37
User entered 'No (N)'	System	03 Sep 2020 23:00:37

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:25', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f0320e17-8524-4c1e-ba01-81277345396d'	System	03 Sep 2020 23:00:37
User entered 'None (1)'	System	03 Sep 2020 23:00:37

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:27', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'f0320e17-8524-4c1e-ba01-81277345396d'	System	03 Sep 2020 23:00:37
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 23:00:37

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 16:15'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 2'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:36', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '744282eb-44dd-406b-b9e5-e1c49d0d4a58'	System	04 Sep 2020 21:58:50
User entered 'None (1)'	System	04 Sep 2020 21:58:50

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:39', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '744282eb-44dd-406b-b9e5-e1c49d0d4a58'	System	04 Sep 2020 21:58:50
User entered 'No (N)'	System	04 Sep 2020 21:58:50

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '744282eb-44dd-406b-b9e5-e1c49d0d4a58'	System	04 Sep 2020 21:58:50
User entered 'No (N)'	System	04 Sep 2020 21:58:50

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '744282eb-44dd-406b-b9e5-e1c49d0d4a58'	System	04 Sep 2020 21:58:50
User entered 'None (1)'	System	04 Sep 2020 21:58:50

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:47', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '744282eb-44dd-406b-b9e5-e1c49d0d4a58'	System	04 Sep 2020 21:58:50
User entered '04 Sep 2020 16:58'	System	04 Sep 2020 21:58:50

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 3'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:45:57', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5ec4751-904a-4614-9aa5-cff4d33f9f5a'	System	06 Sep 2020 00:46:11
User entered 'None (1)'	System	06 Sep 2020 00:46:11

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5ec4751-904a-4614-9aa5-cff4d33f9f5a'	System	06 Sep 2020 00:46:11
User entered 'No (N)'	System	06 Sep 2020 00:46:11

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5ec4751-904a-4614-9aa5-cff4d33f9f5a'	System	06 Sep 2020 00:46:11
User entered 'No (N)'	System	06 Sep 2020 00:46:11

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5ec4751-904a-4614-9aa5-cff4d33f9f5a'	System	06 Sep 2020 00:46:11
User entered 'None (1)'	System	06 Sep 2020 00:46:11

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:08', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5ec4751-904a-4614-9aa5-cff4d33f9f5a'	System	06 Sep 2020 00:46:11
User entered '05 Sep 2020 19:46'	System	06 Sep 2020 00:46:11

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 4'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:37', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd1fb8692-d1c8-4b87-b4d9-6e42663aa10f'	System	06 Sep 2020 23:19:53
User entered 'None (1)'	System	06 Sep 2020 23:19:53

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:40', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd1fb8692-d1c8-4b87-b4d9-6e42663aa10f'	System	06 Sep 2020 23:19:53
User entered 'No (N)'	System	06 Sep 2020 23:19:53

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:42', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd1fb8692-d1c8-4b87-b4d9-6e42663aa10f'	System	06 Sep 2020 23:19:53
User entered 'No (N)'	System	06 Sep 2020 23:19:53

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd1fb8692-d1c8-4b87-b4d9-6e42663aa10f'	System	06 Sep 2020 23:19:53
User entered 'None (1)'	System	06 Sep 2020 23:19:53

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:49', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd1fb8692-d1c8-4b87-b4d9-6e42663aa10f'	System	06 Sep 2020 23:19:53
User entered '06 Sep 2020 18:19'	System	06 Sep 2020 23:19:53

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 5'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9a5b346-d77b-421f-8681-4a6c56e949b3'	System	07 Sep 2020 22:56:56
User entered 'None (1)'	System	07 Sep 2020 22:56:56

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9a5b346-d77b-421f-8681-4a6c56e949b3'	System	07 Sep 2020 22:56:56
User entered 'No (N)'	System	07 Sep 2020 22:56:56

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9a5b346-d77b-421f-8681-4a6c56e949b3'	System	07 Sep 2020 22:56:56
User entered 'No (N)'	System	07 Sep 2020 22:56:56

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:48', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9a5b346-d77b-421f-8681-4a6c56e949b3'	System	07 Sep 2020 22:56:56
User entered 'None (1)'	System	07 Sep 2020 22:56:56

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9a5b346-d77b-421f-8681-4a6c56e949b3'	System	07 Sep 2020 22:56:56
User entered '07 Sep 2020 17:56'	System	07 Sep 2020 22:56:56

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 6'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:39', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '85558306-e54b-4fce-9d43-844c4645a234'	System	08 Sep 2020 20:50:54
User entered 'None (1)'	System	08 Sep 2020 20:50:54

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '85558306-e54b-4fce-9d43-844c4645a234'	System	08 Sep 2020 20:50:54
User entered 'No (N)'	System	08 Sep 2020 20:50:54

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:43', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '85558306-e54b-4fce-9d43-844c4645a234'	System	08 Sep 2020 20:50:54
User entered 'No (N)'	System	08 Sep 2020 20:50:54

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:45', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '85558306-e54b-4fce-9d43-844c4645a234'	System	08 Sep 2020 20:50:54
User entered 'None (1)'	System	08 Sep 2020 20:50:54

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:48', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '85558306-e54b-4fce-9d43-844c4645a234'	System	08 Sep 2020 20:50:54
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 20:50:54

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 7'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:16', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9d26ba9c-35f6-4dc9-b420-e4651f71b60a'	System	09 Sep 2020 20:40:27
User entered 'None (1)'	System	09 Sep 2020 20:40:27

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:18', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9d26ba9c-35f6-4dc9-b420-e4651f71b60a'	System	09 Sep 2020 20:40:27
User entered 'No (N)'	System	09 Sep 2020 20:40:27

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:20', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9d26ba9c-35f6-4dc9-b420-e4651f71b60a'	System	09 Sep 2020 20:40:27
User entered 'No (N)'	System	09 Sep 2020 20:40:27

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9d26ba9c-35f6-4dc9-b420-e4651f71b60a'	System	09 Sep 2020 20:40:27
User entered 'None (1)'	System	09 Sep 2020 20:40:27

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:24', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9d26ba9c-35f6-4dc9-b420-e4651f71b60a'	System	09 Sep 2020 20:40:27
User entered '09 Sep 2020 15:40'	System	09 Sep 2020 20:40:27

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:12:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'None (0)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:12:57', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'None (0)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:13:01', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'None (0)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:13:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'None (0)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:13:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'None (0)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:13:09', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'None (0)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:13:13', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered 'No (N)'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T13:13:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6b07be6e-1cf3-4b29-9376-6723f82bb9fc'	System	03 Sep 2020 18:13:27
User entered '03 Sep 2020 13:13'	System	03 Sep 2020 18:13:27

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 12:50'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 15:20'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:32', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d'	System	03 Sep 2020 23:01:07
User entered 'None (0)'	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:35', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d' User entered 'None (0)'	System	03 Sep 2020 23:01:07
	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:38', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d' User entered 'None (0)'	System	03 Sep 2020 23:01:07
	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d'	System	03 Sep 2020 23:01:07
User entered 'None (0)'	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:43', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d'	System	03 Sep 2020 23:01:07
User entered 'None (0)'	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:45', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d'	System	03 Sep 2020 23:01:07
User entered 'None (0)'	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:49', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d'	System	03 Sep 2020 23:01:07
User entered 'No (N)'	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-03T18:00:58', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e637715c-f9f5-4ac3-8808-88d8155ef60d'	System	03 Sep 2020 23:01:07
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 23:01:07

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '03 Sep 2020 16:15'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 2'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'None (0)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:54', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'None (0)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:57', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'None (0)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:58:59', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'None (0)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:59:01', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'None (0)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:59:03', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'None (0)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:59:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered 'No (N)'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-04T16:59:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '21f5a044-2a42-4455-863d-3d978370d077'	System	04 Sep 2020 21:59:15
User entered '04 Sep 2020 16:59'	System	04 Sep 2020 21:59:15

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 3'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'None (0)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'None (0)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:18', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'None (0)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:20', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'None (0)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'None (0)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:25', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'None (0)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:29', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered 'No (N)'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-05T19:46:31', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a6ca169f-da1b-4866-b1e8-5d32ec6899e1'	System	06 Sep 2020 00:46:35
User entered '05 Sep 2020 19:46'	System	06 Sep 2020 00:46:35

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 4'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:17', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'None (0)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:20', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'None (0)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:22', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'None (0)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:24', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'None (0)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:26', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'None (0)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'None (0)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:31', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered 'No (N)'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-06T18:19:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '3fa14f41-05ee-43bf-beab-986126dd12e7'	System	06 Sep 2020 23:19:36
User entered '06 Sep 2020 18:19'	System	06 Sep 2020 23:19:36

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 5'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:54', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'None (0)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:56', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'None (0)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:56:58', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'None (0)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:57:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'None (0)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:57:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'None (0)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:57:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'None (0)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:57:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered 'No (N)'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-07T17:57:09', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '9f37a51b-1345-40e5-bda2-f8285eceda50'	System	07 Sep 2020 22:57:14
User entered '07 Sep 2020 17:57'	System	07 Sep 2020 22:57:14

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 6'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:51', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'None (0)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:53', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'None (0)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'None (0)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:57', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'None (0)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:50:59', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'None (0)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:51:01', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'None (0)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:51:03', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered 'No (N)'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-08T15:51:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '0c520833-46cc-4741-abc0-b930a954d2d6'	System	08 Sep 2020 20:51:09
User entered '08 Sep 2020 15:51'	System	08 Sep 2020 20:51:09

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	03 Sep 2020 17:43:41
User entered 'Day 7'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:27', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'None (0)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:29', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'None (0)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:31', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'None (0)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'None (0)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:35', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'None (0)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:37', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'None (0)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

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 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:39', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered 'No (N)'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-09-09T15:40:42', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4201e6a1-5ef2-4a45-923a-fe767d6df85a'	System	09 Sep 2020 20:40:50
User entered '09 Sep 2020 15:40'	System	09 Sep 2020 20:40:50

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 17:43:41

US3092043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 17:43:41

US3092043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:45

US3092043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:45

US3092043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:45

US3092043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:45

US3092043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:33:29

US3092043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	07 Oct 2020 20:33:29

US3092043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:39

US3092043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:39

US3092043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:39

US3092043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:39

US3092043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:33:40

US3092043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	07 Oct 2020 20:33:40

US3092043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:33

US3092043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:33

US3092043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:33

US3092043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:38:33

US3092043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:33:50

US3092043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	07 Oct 2020 20:33:50

US3092043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:34:04

US3092043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '7 Oct 2020'	Catina Adams (b) (4)	07 Oct 2020 20:34:04

US3092043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	07 Oct 2020 20:34:04

US3092043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'VISIT3'	System	07 Oct 2020 20:34:04

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '7 Oct 2020'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:45'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '7 Oct 2020 14:45'	System	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '98.6' F	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (Oral)'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '82'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'bpm'	System	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '18'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'breaths/min'	System	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '137'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '88'	Catina Adams (b) (4)	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'mmHg'	System	07 Oct 2020 20:35:02

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22

US3092043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22

US3092043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:35:16

US3092043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '7 Oct 2020'	Catina Adams (b) (4)	07 Oct 2020 20:35:16

US3092043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:42:50

US3092043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '7 Oct 2020'	Catina Adams (b) (4)	07 Oct 2020 20:42:50

US3092043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '15:36'	Catina Adams (b) (4)	07 Oct 2020 20:42:50

US3092043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered '7 Oct 2020 15:36'	System	07 Oct 2020 20:42:50

US3092043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 20:35:24

US3092043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	07 Oct 2020 20:35:24

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 64'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-10-06T16:29:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '433837ee-f916-42c0-a6eb-762961e0b661'	System	06 Oct 2020 21:29:43
User entered 'No (N)'	System	06 Oct 2020 21:29:43

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-10-06T16:29:32', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '433837ee-f916-42c0-a6eb-762961e0b661'	System	06 Oct 2020 21:29:43
User entered 'No (N)'	System	06 Oct 2020 21:29:43

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0f9a822ffe79294)', Time: '2020-10-06T16:29:38', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '433837ee-f916-42c0-a6eb-762961e0b661'	System	06 Oct 2020 21:29:43
User entered '06 Oct 2020 16:29:38'	System	06 Oct 2020 21:29:43

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 71'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 78'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 92'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:13:37
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 99'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-11-11T09:19:19', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6e9b812d-56c1-49b2-a591-fcaf3797b607'	System	11 Nov 2020 15:19:23
User entered 'No (N)'	System	11 Nov 2020 15:19:23

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-11-11T09:19:21', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6e9b812d-56c1-49b2-a591-fcaf3797b607'	System	11 Nov 2020 15:19:23
User entered 'No (N)'	System	11 Nov 2020 15:19:23

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-11-11T09:19:24', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6e9b812d-56c1-49b2-a591-fcaf3797b607'	System	11 Nov 2020 15:19:23
User entered '11 Nov 2020 09:19:24'	System	11 Nov 2020 15:19:23

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered 'Day 106'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-11-17T09:04:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5416597-92d9-4c01-8984-ece6795eebf5'	System	17 Nov 2020 15:04:18
User entered 'No (N)'	System	17 Nov 2020 15:04:18

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-11-17T09:04:10', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5416597-92d9-4c01-8984-ece6795eebf5'	System	17 Nov 2020 15:04:18
User entered 'No (N)'	System	17 Nov 2020 15:04:18

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-11-17T09:04:19', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a5416597-92d9-4c01-8984-ece6795eebf5'	System	17 Nov 2020 15:04:18
User entered '17 Nov 2020 09:04:19'	System	17 Nov 2020 15:04:18

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 21:11:28

US3092043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:06:21
Data entry locked.	System	06 Aug 2020 21:11:28
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 21:11:28

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-02T11:22:14', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2fd96f4a-6b2b-496c-97b5-8b9fdf3694a2'	System	02 Dec 2020 17:22:23
User entered 'No (N)'	System	02 Dec 2020 17:22:23

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-02T11:22:19', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2fd96f4a-6b2b-496c-97b5-8b9fdf3694a2'	System	02 Dec 2020 17:22:23
User entered 'No (N)'	System	02 Dec 2020 17:22:23

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-02T11:22:23', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '2fd96f4a-6b2b-496c-97b5-8b9fdf3694a2'	System	02 Dec 2020 17:22:23
User entered '02 Dec 2020 11:22:23'	System	02 Dec 2020 17:22:23

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-07T21:04:23', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ff813de3-f071-48ea-bb63-d62a702e6318'	System	08 Dec 2020 03:04:26
User entered 'No (N)'	System	08 Dec 2020 03:04:26

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-07T21:04:25', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ff813de3-f071-48ea-bb63-d62a702e6318'	System	08 Dec 2020 03:04:26
User entered 'No (N)'	System	08 Dec 2020 03:04:26

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-07T21:04:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'ff813de3-f071-48ea-bb63-d62a702e6318' User entered '07 Dec 2020 21:04:28'	System	08 Dec 2020 03:04:26
	System	08 Dec 2020 03:04:26

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-12T00:02:30', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '735c2152-06b1-44de-b045-22a33938f15f'	System	12 Dec 2020 06:02:41
User entered 'No (N)'	System	12 Dec 2020 06:02:41

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-12T00:02:33', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '735c2152-06b1-44de-b045-22a33938f15f'	System	12 Dec 2020 06:02:41
User entered 'No (N)'	System	12 Dec 2020 06:02:41

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-12T00:02:36', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '735c2152-06b1-44de-b045-22a33938f15f' User entered '12 Dec 2020 00:02:36'	System	12 Dec 2020 06:02:41

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-19T00:34:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44bb5317-2310-4118-ab7c-1dcaf5a8a6e8'	System	19 Dec 2020 06:34:54
User entered 'No (N)'	System	19 Dec 2020 06:34:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-19T00:34:48', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44bb5317-2310-4118-ab7c-1dcaf5a8a6e8'	System	19 Dec 2020 06:34:54
User entered 'No (N)'	System	19 Dec 2020 06:34:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8e235d223c1c56c3)', Time: '2020-12-19T00:34:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '44bb5317-2310-4118-ab7c-1dcaf5a8a6e8'	System	19 Dec 2020 06:34:54
User entered '19 Dec 2020 00:34:52'	System	19 Dec 2020 06:34:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2020-12-29T09:15:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '5ea6358f-baeb-4a0a-8766-a6ec52514a64'	System	29 Dec 2020 15:15:53
User entered 'No (N)'	System	29 Dec 2020 15:15:53

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2020-12-29T09:15:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '5ea6358f-baeb-4a0a-8766-a6ec52514a64'	System	29 Dec 2020 15:15:53
User entered 'No (N)'	System	29 Dec 2020 15:15:53

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2020-12-29T09:15:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '5ea6358f-baeb-4a0a-8766-a6ec52514a64'	System	29 Dec 2020 15:15:53
User entered '29 Dec 2020 09:15:55'	System	29 Dec 2020 15:15:53

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-02T17:00:09', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4b07f089-985a-49a7-ae41-9c1a0bcfb6cc'	System	02 Jan 2021 23:00:16
User entered 'No (N)'	System	02 Jan 2021 23:00:16

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-02T17:00:12', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4b07f089-985a-49a7-ae41-9c1a0bcfb6cc'	System	02 Jan 2021 23:00:16
User entered 'No (N)'	System	02 Jan 2021 23:00:16

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-02T17:00:15', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4b07f089-985a-49a7-ae41-9c1a0bcfb6cc'	System	02 Jan 2021 23:00:16
User entered '02 Jan 2021 17:00:15'	System	02 Jan 2021 23:00:16

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-10T20:55:52', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'cf75d599-1e2f-4b8b-ae2c-196adc519354'	System	11 Jan 2021 02:56:06
User entered 'No (N)'	System	11 Jan 2021 02:56:06

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-10T20:55:55', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'cf75d599-1e2f-4b8b-ae2c-196adc519354'	System	11 Jan 2021 02:56:06
User entered 'No (N)'	System	11 Jan 2021 02:56:06

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-10T20:56:02', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'cf75d599-1e2f-4b8b-ae2c-196adc519354' User entered '10 Jan 2021 20:56:02'	System	11 Jan 2021 02:56:06
	System	11 Jan 2021 02:56:06

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-16T00:03:38', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9d39852-976b-4a32-b542-4f8cbaf2c268'	System	16 Jan 2021 06:03:47
User entered 'No (N)'	System	16 Jan 2021 06:03:47

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-16T00:03:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9d39852-976b-4a32-b542-4f8cbaf2c268'	System	16 Jan 2021 06:03:47
User entered 'No (N)'	System	16 Jan 2021 06:03:47

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-16T00:03:43', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'e9d39852-976b-4a32-b542-4f8cbaf2c268' User entered '16 Jan 2021 00:03:43'	System	16 Jan 2021 06:03:47
	System	16 Jan 2021 06:03:47

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-24T09:48:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b21cac8c-8954-49c1-b43e-8036acc48930'	System	24 Jan 2021 15:48:11
User entered 'No (N)'	System	24 Jan 2021 15:48:11

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-24T09:48:04', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b21cac8c-8954-49c1-b43e-8036acc48930'	System	24 Jan 2021 15:48:11
User entered 'No (N)'	System	24 Jan 2021 15:48:11

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-24T09:48:08', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b21cac8c-8954-49c1-b43e-8036acc48930' User entered '24 Jan 2021 09:48:08'	System	24 Jan 2021 15:48:11

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-30T01:13:44', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8c408e9b-aa64-4dc4-9ba6-9ade0c6bacc7'	System	30 Jan 2021 07:13:51
User entered 'No (N)'	System	30 Jan 2021 07:13:51

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-30T01:13:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8c408e9b-aa64-4dc4-9ba6-9ade0c6bacc7'	System	30 Jan 2021 07:13:51
User entered 'No (N)'	System	30 Jan 2021 07:13:51

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-01-30T01:13:49', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '8c408e9b-aa64-4dc4-9ba6-9ade0c6bacc7'	System	30 Jan 2021 07:13:51
User entered '30 Jan 2021 01:13:49'	System	30 Jan 2021 07:13:51

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-07T23:30:25', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '285f7900-cec3-4c1b-abe6-544080ca4edd'	System	08 Feb 2021 05:30:31
User entered 'No (N)'	System	08 Feb 2021 05:30:31

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-07T23:30:28', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '285f7900-cec3-4c1b-abe6-544080ca4edd'	System	08 Feb 2021 05:30:31
User entered 'No (N)'	System	08 Feb 2021 05:30:31

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-07T23:30:31', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '285f7900-cec3-4c1b-abe6-544080ca4edd' User entered '07 Feb 2021 23:30:31'	System	08 Feb 2021 05:30:31
	System	08 Feb 2021 05:30:31

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-13T00:02:01', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6c8191fb-7d59-4173-8c45-0e675957d3de'	System	13 Feb 2021 06:02:19
User entered 'No (N)'	System	13 Feb 2021 06:02:19

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-13T00:02:03', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6c8191fb-7d59-4173-8c45-0e675957d3de'	System	13 Feb 2021 06:02:19
User entered 'No (N)'	System	13 Feb 2021 06:02:19

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-13T00:02:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6c8191fb-7d59-4173-8c45-0e675957d3de'	System	13 Feb 2021 06:02:19
User entered '13 Feb 2021 00:02:06'	System	13 Feb 2021 06:02:19

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-21T20:31:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'fe10f909-fea6-4814-aace-b6ebd6c641b2'	System	22 Feb 2021 02:31:14
User entered 'No (N)'	System	22 Feb 2021 02:31:14

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-21T20:31:11', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'fe10f909-fea6-4814-aace-b6ebd6c641b2'	System	22 Feb 2021 02:31:14
User entered 'No (N)'	System	22 Feb 2021 02:31:14

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-02-21T20:31:14', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'fe10f909-fea6-4814-aace-b6ebd6c641b2'	System	22 Feb 2021 02:31:14
User entered '21 Feb 2021 20:31:14'	System	22 Feb 2021 02:31:14

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-01T12:00:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '5ff8f502-4b93-4d02-8112-d5926ad79fa6'	System	01 Mar 2021 18:03:52
User entered 'No (N)'	System	01 Mar 2021 18:03:52

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-01T12:00:54', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '5ff8f502-4b93-4d02-8112-d5926ad79fa6'	System	01 Mar 2021 18:03:52
User entered 'No (N)'	System	01 Mar 2021 18:03:52

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-01T12:01:06', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '5ff8f502-4b93-4d02-8112-d5926ad79fa6'	System	01 Mar 2021 18:03:52
User entered '01 Mar 2021 12:01:06'	System	01 Mar 2021 18:03:52

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-06T00:01:41', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '318320ab-2666-499e-bdb4-26e9eb809c94'	System	06 Mar 2021 06:10:23
User entered 'No (N)'	System	06 Mar 2021 06:10:23

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-06T00:01:46', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '318320ab-2666-499e-bdb4-26e9eb809c94'	System	06 Mar 2021 06:10:23
User entered 'No (N)'	System	06 Mar 2021 06:10:23

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-06T00:01:50', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '318320ab-2666-499e-bdb4-26e9eb809c94'	System	06 Mar 2021 06:10:23
User entered '06 Mar 2021 00:01:50'	System	06 Mar 2021 06:10:23

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-13T00:08:42', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '93868703-7fd3-4e15-a541-b2de5ca34f0c'	System	13 Mar 2021 06:08:50
User entered 'No (N)'	System	13 Mar 2021 06:08:50

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-13T00:08:45', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '93868703-7fd3-4e15-a541-b2de5ca34f0c'	System	13 Mar 2021 06:08:50
User entered 'No (N)'	System	13 Mar 2021 06:08:50

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-13T00:08:48', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '93868703-7fd3-4e15-a541-b2de5ca34f0c'	System	13 Mar 2021 06:08:50
User entered '13 Mar 2021 00:08:48'	System	13 Mar 2021 06:08:50

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-20T15:40:07', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b35db183-e099-416a-83a5-e9f8d5e9df88'	System	20 Mar 2021 20:40:13
User entered 'No (N)'	System	20 Mar 2021 20:40:13

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-20T15:40:09', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b35db183-e099-416a-83a5-e9f8d5e9df88'	System	20 Mar 2021 20:40:13
User entered 'No (N)'	System	20 Mar 2021 20:40:13

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-20T15:40:11', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'b35db183-e099-416a-83a5-e9f8d5e9df88'	System	20 Mar 2021 20:40:13
User entered '20 Mar 2021 15:40:11'	System	20 Mar 2021 20:40:13

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-27T12:33:49-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '790406d3-e289-4c37-be57-1154d830d4c9'	System	27 Mar 2021 17:33:54
User entered 'No (N)'	System	27 Mar 2021 17:33:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-27T12:33:51-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '790406d3-e289-4c37-be57-1154d830d4c9'	System	27 Mar 2021 17:33:54
User entered 'No (N)'	System	27 Mar 2021 17:33:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-27T12:33:54-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '790406d3-e289-4c37-be57-1154d830d4c9' User entered '27 Mar 2021 12:33:54'	System	27 Mar 2021 17:33:54
	System	27 Mar 2021 17:33:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-07T10:41:48-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7772221b-b1db-4bdf-b5e8-fa359125aeb3'	System	07 Apr 2021 15:42:01
User entered 'No (N)'	System	07 Apr 2021 15:42:01

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-07T10:41:51-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7772221b-b1db-4bdf-b5e8-fa359125aeb3'	System	07 Apr 2021 15:42:01
User entered 'No (N)'	System	07 Apr 2021 15:42:01

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-07T10:41:53-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '7772221b-b1db-4bdf-b5e8-fa359125aeb3'	System	07 Apr 2021 15:42:01
User entered '07 Apr 2021 10:41:53'	System	07 Apr 2021 15:42:01

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-10T01:28:54-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a93d99f5-73d5-45db-837d-e5518fe9768b' User entered 'No (N)'	System	10 Apr 2021 06:29:14
	System	10 Apr 2021 06:29:14

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-10T01:28:57-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a93d99f5-73d5-45db-837d-e5518fe9768b' User entered 'No (N)'	System	10 Apr 2021 06:29:14
	System	10 Apr 2021 06:29:14

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-10T01:29:15-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'a93d99f5-73d5-45db-837d-e5518fe9768b' User entered '10 Apr 2021 01:29:15'	System	10 Apr 2021 06:29:14
	System	10 Apr 2021 06:29:14

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-17T01:10:47-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6d923b44-efe4-4a8b-affd-06a8dcf17f75'	System	17 Apr 2021 06:10:54
User entered 'No (N)'	System	17 Apr 2021 06:10:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-17T01:10:49-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6d923b44-efe4-4a8b-affd-06a8dcf17f75'	System	17 Apr 2021 06:10:54
User entered 'No (N)'	System	17 Apr 2021 06:10:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-17T01:10:52-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '6d923b44-efe4-4a8b-affd-06a8dcf17f75'	System	17 Apr 2021 06:10:54
User entered '17 Apr 2021 01:10:52'	System	17 Apr 2021 06:10:54

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-24T01:54:47-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4b3fffeb-f861-4957-90e5-d325541d6356'	System	24 Apr 2021 06:54:59
User entered 'No (N)'	System	24 Apr 2021 06:54:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-24T01:54:51-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4b3fffeb-f861-4957-90e5-d325541d6356'	System	24 Apr 2021 06:54:59
User entered 'No (N)'	System	24 Apr 2021 06:54:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-04-24T01:54:59-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '4b3fffeb-f861-4957-90e5-d325541d6356'	System	24 Apr 2021 06:54:59
User entered '24 Apr 2021 01:54:59'	System	24 Apr 2021 06:54:59

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-05-01T00:02:03-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '1252625d-ee7e-4d9f-b684-f98e80c186fd'	System	01 May 2021 05:16:22
User entered 'No (N)'	System	01 May 2021 05:16:22

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-05-01T00:02:06-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '1252625d-ee7e-4d9f-b684-f98e80c186fd'	System	01 May 2021 05:16:22
User entered 'No (N)'	System	01 May 2021 05:16:22

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-05-01T00:02:09-05:00', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: '1252625d-ee7e-4d9f-b684-f98e80c186fd' User entered '01 May 2021 00:02:09'	System	01 May 2021 05:16:22
	System	01 May 2021 05:16:22

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:13:37

US3092043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:13:37
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:13:37

US3092043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:05:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-01T12:00:29', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd7d646ea-46e4-4735-bfc0-816b47a02cf9'	System	01 Mar 2021 18:00:59
User entered 'No (N)'	System	01 Mar 2021 18:00:59

US3092043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:05:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13d9b87c1f656ec3)', Time: '2021-03-01T12:00:38', User OID: 'PatientReportedOutcome (US3092043)', ODM File OID: 'd7d646ea-46e4-4735-bfc0-816b47a02cf9'	System	01 Mar 2021 18:00:59
User entered '01 Mar 2021 12:00:38'	System	01 Mar 2021 18:00:59

US3092043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:48:18

US3092043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:42:58
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm and correct ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 16:48:27
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Nov 2020 16:48:18
User entered '09 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 16:48:18

US3092043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:48:18

US3092043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:48:18

US3092043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:48:32

US3092043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:47:22
User entered 'I'	System	16 Nov 2020 16:48:32

US3092043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	03 Dec 2020 13:33:00

US3092043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '2 Dec 2020'	Catina Adams (b) (4)	03 Dec 2020 13:33:00

US3092043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	03 Dec 2020 13:33:00

US3092043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Catina Adams (b) (4)	03 Dec 2020 13:33:00

US3092043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Catina Adams (b) (4)	03 Dec 2020 13:32:45

US3092043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'I'	System	03 Dec 2020 13:32:45

US3092043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:33

US3092043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:33

US3092043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:33

US3092043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:33

US3092043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:39

US3092043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'I'	System	30 Dec 2020 17:28:39

US3092043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:51:45

US3092043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:51:45

US3092043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:51:45

US3092043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:51:45

US3092043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:51:50

US3092043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'I'	System	29 Jan 2021 18:51:50

US3092043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:09

US3092043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:09

US3092043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:09

US3092043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'VISIT4'	System	16 Mar 2021 15:25:09

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered 'Yes (Y)'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '23 Feb 2021'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '13:05'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered '23 Feb 2021 13:05'	System	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '98.6' F	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered 'Oral (Oral)'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered empty.	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '100'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'bpm'	System	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '18'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'breaths/min'	System	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '105'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'mmHg'	System	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '63'	Catina Adams (b) (4)	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'mmHg'	System	30 Mar 2021 21:41:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53

US3092043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53

US3092043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:55:33
User entered 'Yes (Y)' reason for change: Data Entry Error		30 Mar 2021 21:55:33
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:55:33
User entered '23 Feb 2021' reason for change: Data Entry Error		30 Mar 2021 21:55:33
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:25

US3092043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:56:08
User entered 'Yes (Y)' reason for change: Data Entry Error		30 Mar 2021 21:56:08
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:30

US3092043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:56:08
User entered '23 Feb 2021' reason for change: Data Entry Error		30 Mar 2021 21:56:08
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:30

US3092043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:56:08
User entered '13:40' reason for change: Data Entry Error		30 Mar 2021 21:56:08
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:30

US3092043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered '23 Feb 2021 13:40'	System	30 Mar 2021 21:56:08
User entered empty.	System	16 Mar 2021 15:25:30

US3092043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:25:35

US3092043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:53
User entered 'I'	System	16 Mar 2021 15:25:35

US3092043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:15
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:11:37

US3092043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:15
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:11:37

US3092043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:15
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:11:37

US3092043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:15
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:11:37

US3092043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:15
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:12:05

US3092043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:15
User entered 'I'	System	30 Mar 2021 18:12:05

US3092043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 14:04:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:47:05

US3092043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 14:04:40
User entered '28 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:47:05

US3092043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 14:04:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:47:05

US3092043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 14:04:40
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:47:05

US3092043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 14:04:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:49:07

US3092043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 13:49:07

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:33

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:33

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:33

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:52:33

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:33:44

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:33:44

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:35:03
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:35:03
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '1'	System	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:05:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'I'	System	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '166.0' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '197.8' lb	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '32.62777'	System	19 Jan 2021 21:54:16
DataPoint set to visible.	System	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '166.0' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '197.8' lb	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '32.62777'	System	19 Jan 2021 21:54:16
DataPoint set to visible.	System	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User accepted default value 'Pre-Dose (PREDOSE)'		19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:20'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '19 Jan 2021 14:20'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '90'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'bpm'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'breaths/min'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '135'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '86'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '166.0' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '197.8' lb	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '32.62777'	System	19 Jan 2021 21:54:16
DataPoint set to visible.	System	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User accepted default value 'Post-Dose (POSTDOSE)'		19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '15:19'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '19 Jan 2021 15:19'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '84'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'bpm'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'breaths/min'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '135'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '82'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	19 Jan 2021 21:54:16

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:36

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:36

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mRNA-1273'	System	19 Jan 2021 21:54:56
DataPoint set to visible.	System	19 Jan 2021 21:52:52

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:47'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '19 Jan 2021 14:47'	System	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'ONCE'	System	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 21:54:56

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:12

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:12

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:42'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:12

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '19 Jan 2021 14:42'	System	19 Jan 2021 21:55:12

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:22

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:26

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:22

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '14:39'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:22

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '19 Jan 2021 14:39'	System	19 Jan 2021 21:55:22

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:55:27

US3092043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '1'	System	19 Jan 2021 21:55:27

US3092043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:59:11

US3092043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:59:11

US3092043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:59:11

US3092043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '1ST ATTEMPT ON 01/27/21/ NO ANSWER 2ND ATTEMPT ON 01/28/21 CONTACT MADE'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:59:11

US3092043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:59:15

US3092043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'I'	System	28 Jan 2021 17:59:15

US3092043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '1'	System	28 Jan 2021 17:59:15
DataPoint set to visible.	System	28 Jan 2021 17:59:15

US3092043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:04:56

US3092043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:04:56

US3092043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:04:56

US3092043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'OLD29'	System	24 Feb 2021 22:04:56

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User accepted default value 'Pre-Dose (PREDOSE)'		24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '13:05'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '23 Feb 2021 13:05'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '100'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'bpm'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'breaths/min'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '105'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '63'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User accepted default value 'Post-Dose (POSTDOSE)'		24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '14:15'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '23 Feb 2021 14:15'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '98'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'bpm'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'breaths/min'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '135'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '79'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	24 Feb 2021 22:06:44

US3092043

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:07:28

US3092043

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:07:28

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mRNA-1273'	System	24 Feb 2021 22:08:07
DataPoint set to visible.	System	28 Jan 2021 17:59:15

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '13:43'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '23 Feb 2021 13:43'	System	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'ONCE'	System	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 22:08:07

US3092043

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:08:13

US3092043

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'I'	System	24 Feb 2021 22:08:13

US3092043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:39:09

US3092043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:39:09

US3092043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:39:09

US3092043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:39:09

US3092043

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:39:29

US3092043

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'I'	System	04 Mar 2021 17:39:29

US3092043

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:23:15

US3092043

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:23:15

US3092043

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:23:15

US3092043

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'OLD57'	System	25 Mar 2021 22:23:15

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '13:15'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '24 Mar 2021 13:15'	System	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '87'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'bpm'	System	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'breaths/min'	System	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '128'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '86'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered 'mmHg'	System	25 Mar 2021 22:24:18

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47

US3092043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47

US3092043

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:28

US3092043

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:28

US3092043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:48

US3092043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:48

US3092043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 00:59:56
User entered '13:40'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 22:24:48

US3092043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:21:47
User entered '24 Mar 2021 13:40'	System	25 Mar 2021 22:24:48

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:26

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:06

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:26

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:06

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:26

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:06

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:26

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:06

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:26

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:06

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:30

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:30

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User entered '13:40'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:26:30

US3092043

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:49:10
User entered '23 Feb 2021 13:40'	System	16 Mar 2021 15:26:30

US3092043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:05:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:55
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:15:45
User entered 'Yes (Y)' reason for change: Data Entry Error	destiny robinson (b) (4)	12 Nov 2020 20:47:11
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:33:22

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:11:42
Reviewed for Safety.		19 Nov 2020 13:29:11
User entered 'USA-US086-2020-mRNA-1273-P301000005'	System	19 Nov 2020 13:29:04
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 13:29:04

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:11:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 19:47:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 19:47:47
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 19:46:44
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	18 Nov 2020 19:46:02
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'DONE' (Site from System).	Marissa Cervenka (b) (4)	18 Nov 2020 19:46:02
	(b) (4)	
DataPoint Un-verified.	Marissa Cervenka (b) (4)	18 Nov 2020 19:45:43
	(b) (4)	
User entered 'ASTHMA EXACERBATION' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 19:45:43
	(b) (4)	
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	12 Nov 2020 23:22:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:31
Data point term sent to Coder	System	12 Nov 2020 21:08:26
User entered 'asthma/chronic obstructive pulmonary disease exacerbation'	destiny robinson (b) (4)	12 Nov 2020 21:07:33
	(b) (4)	

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 21:08:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 21:08:34
User entered 'No (N)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:08:34
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 21:07:33
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:24
DataPoint Un-verified.		06 Apr 2021 16:17:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '2 Oct 2020'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User closed query 'Per source, there is a stop date of 10Nov20, please review and make necessary corrections.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:55:06
Query 'Per source, there is a stop date of 10Nov20, please review and make necessary corrections.' answered with 'Updated' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6) Catina Adams (b) (4) (b) (4)	24 Nov 2020 22:54:55 24 Nov 2020 22:37:36
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	24 Nov 2020 22:37:25
User opened query 'Per source, there is a stop date of 10Nov20, please review and make necessary corrections.' (Site from CRA). DataPoint Verified.	Catina Adams (b) (4) (b) (4), (b) (6)	24 Nov 2020 22:37:25
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:11:05
DataPoint Verified.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Nov 2020 21:08:45
User entered 'No (N)' reason for change: Data Entry Error	System destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:08:45
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Nov 2020 21:08:34
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:21:35
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:11:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:54:57
DataPoint Un-verified.	Catina Adams (b) (4)	24 Nov 2020 22:37:25
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Catina Adams (b) (4)	24 Nov 2020 22:37:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:11:03
DataPoint Un-verified.	Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
User entered empty; reason for change Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Nov 2020 21:08:34
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	12 Nov 2020 21:08:34
User entered '10 Nov 2020' reason for change: Data Entry Error	destiny robinson (b) (4)	12 Nov 2020 21:08:34
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4) System	12 Nov 2020 21:07:33
User entered empty.	destiny robinson (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:11:51
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4)	12 Nov 2020 21:07:33
	(b) (4)	

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:10:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 16:43:17
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'done' (Site from System).	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 21:05:07
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07
User entered '1' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:46
DataPoint Un-verified.		12 Nov 2020 21:34:43
DataPoint Verified.		12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:16:09
DataPoint Un-verified.		06 Apr 2021 16:09:16
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:10:41
DataPoint Un-verified.	Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:48
DataPoint Un-verified.		12 Nov 2020 21:34:38
DataPoint Verified.		12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:16:11
DataPoint Un-verified.		06 Apr 2021 16:09:14
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:10:43
DataPoint Un-verified.	Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 21:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:49
DataPoint Un-verified.		12 Nov 2020 21:34:40
DataPoint Verified.		12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'Not Related (NOT RELATED)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'Not Related (NOT RELATED)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 21:08:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 21:08:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:08:34
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 21:07:33
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4)	12 Nov 2020 21:07:33
	(b) (4)	

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
Query 'Per CDM: 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' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 12:35:27
User opened query 'Per CDM: 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) (6)	10 Feb 2021 12:32:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'I'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:24:38
User closed query 'Source doesn't Match, please confirm if Asthma Exacerbation is resolved and add end date. Please review AE Log.' (Site from CRA). DataPoint Verified.		24 Nov 2020 22:55:30
		24 Nov 2020 22:55:26
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'Updated' (Site from Safety).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 22:38:43
Query 'Source doesn't Match, please confirm if Asthma Exacerbation is resolved and add end date. Please review AE Log.' answered with 'Updated' (Site from CRA).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 22:37:50
DataPoint Un-verified.	Catina Adams (b) (4) (b) (4)	24 Nov 2020 22:37:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	24 Nov 2020 22:37:25
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:08:19
User opened query 'Source doesn't Match, please confirm if Asthma Exacerbation is resolved and add end date. Please review AE Log.' (Site from CRA). DataPoint Verified.		19 Nov 2020 18:48:08
		19 Nov 2020 18:47:52
DataPoint Un-verified.		19 Nov 2020 18:47:48
DataPoint Verified.		19 Nov 2020 17:30:18
DataPoint Un-verified.		19 Nov 2020 17:30:15
DataPoint Verified.		19 Nov 2020 17:10:53
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:05:07

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	destiny robinson (b) (4)	12 Nov 2020 21:07:33
	(b) (4)	

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:34:31
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:53:54
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 17:53:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. Please leave query open until information is available. ' answered with 'Medical records have been requested on four different occasions and still have not been received.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:03:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Medical records have been requested four different times and still have not been received.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:02:59
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:05:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'we have requested medical records several times and have not recieved any back' (Site from Safety).	destiny robinson (b) (4) (b) (4)	10 Feb 2021 16:14:23

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:25:23
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. ' (Site from Safety).		14 Dec 2020 15:17:30
User closed query 'PV Query: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is reported as 'Yes. Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).		14 Dec 2020 15:17:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. ' answered with 'This event is NOT Symptomatic Covid-19. Hospital records have been requested 3 times. A 4th request was send to the hospital today (11 DEC 2020) All requested information and queries for this event will be updated upon receipt of hospital records. ' (Site from Safety).	Marissa Cervenka (b) (4) (b) (4)	11 Dec 2020 18:39:49
Query 'PV Query: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is reported as 'Yes. Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'This event is NOT Symptomatic Covid-19' (Site from Safety).	Marissa Cervenka (b) (4) (b) (4)	11 Dec 2020 18:36:51
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. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 17:23:36
User opened query 'PV Query: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is reported as 'Yes. Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).		01 Dec 2020 17:23:12

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[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.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 17:21:44
User closed query 'PV Query: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is reported as 'Yes. Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:24:26
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. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:24:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:24:07
User closed query 'PV Query: Please confirm the subject's date of birth (It is reported as (b) (6) 1950 in the screening document and (b) (6) 1950 in the adverse event form)' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:24:02
Query 'PV Query: Please confirm the subject's date of birth (It is reported as (b) (6) 1950 in the screening document and (b) (6) 1950 in the adverse event form)' answered with 'Updated' (Site from Safety).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:05:48
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Waiting on hospital discharge summary to answer question.' (Site from Safety).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:03:28
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. ' answered with 'Waiting on hospital discharge summary to answer question.' (Site from Safety).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:02:38

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is reported as 'Yes. Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'Waiting on hospital discharge summary to answer question.' (Site from Safety).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:01:59
Query 'PV Query: Please add concomitant medication received within 30 days prior to event to concomitant medication eCRF . If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:50:06
User opened query 'PV Query: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is reported as 'Yes. Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).		20 Nov 2020 18:07:58
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. ' (Site from Safety).		20 Nov 2020 18:07:46
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		20 Nov 2020 18:07:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:07:21
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event to concomitant medication eCRF . If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:07:13
User opened query 'PV Query: Please confirm the subject's date of birth (It is reported as (b) (6) 1950 in the screening document and (b) (6) 1950 in the adverse event form)' (Site from Safety).		20 Nov 2020 18:07:06
DataPoint Verified.		12 Nov 2020 21:34:31

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject reported hospitalization for COPD Asthma Exacerbation. Subject was admitted on 28 October 2020 and discharged 4 november 2020. medical records have been requested. additional information will be provided upon receiving medical records.' reason for change: Data Entry Error	destiny robinson (b) (4)	12 Nov 2020 21:12:09
User entered 'used prednisone medication'	destiny robinson (b) (4)	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 21:05:07
User entered '0'	System	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 21:07:33

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
Reviewed for Safety.		19 Nov 2020 13:29:49
User entered 'USA-US086-2020-mRNA-1273-P301000005'		19 Nov 2020 13:29:43

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:49:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 20:05:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 20:05:49
Data point term sent to Coder	System	18 Nov 2020 20:05:08
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION'	Marissa Cervenka (b) (4)	18 Nov 2020 20:04:28
	(b) (4)	

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '02 Oct 2020'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:40:31
User closed query 'Per source, there is a stop date of 10Nov20, please review and make necessary corrections.' (Site from CRA).		17 Dec 2020 18:40:30
Query 'Per source, there is a stop date of 10Nov20, please review and make necessary corrections.' answered with 'Updated' (Site from CRA).	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:15:45
DataPoint Un-verified.	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:15:27
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	24 Nov 2020 23:15:27
User opened query 'Per source, there is a stop date of 10Nov20, please review and make necessary corrections.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:50:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:48:52
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:40:33
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 23:15:27
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 23:15:27
DataPoint Un-verified.	Catina Adams (b) (4)	24 Nov 2020 23:15:27
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Catina Adams (b) (4)	24 Nov 2020 23:15:27
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 23:14:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:23
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 20:49:24
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 20:49:24
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 20:48:52
User entered empty; reason for change Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 20:48:52
User entered '10 Nov 2020'	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '28 Oct 2020'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '04 Nov 2020'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
Query 'Per CDM: 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' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 12:35:19
User opened query 'Per CDM: 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) (6)	10 Feb 2021 12:32:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:41:19
User closed query 'Source doesn't Match, please confirm COPD Exacerbation is resolved and add end date. Please review AE Log.' (Site from CRA). User signature succeeded.	(b) (4)	30 Mar 2021 19:41:06
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:25:02
Query 'Source doesn't Match, please confirm COPD Exacerbation is resolved and add end date. Please review AE Log.' answered with 'Updated' (Site from CRA).	Catina Adams (b) (4)	24 Nov 2020 23:16:53
DataPoint Un-verified.	(b) (4)	24 Nov 2020 23:16:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Nov 2020 23:14:54
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:08:57
User opened query 'Source doesn't Match, please confirm COPD Exacerbation is resolved and add end date. Please review AE Log.' (Site from CRA).	(b) (4)	19 Nov 2020 18:50:12
DataPoint Verified.	(b) (4)	19 Nov 2020 18:49:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 20:49:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marissa Cervenka (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:49:23
User entered 'Visit Day 57 the subject reported exacerbation which started on 2 Oct 2020. At Day 85 phone call the subject informed the site that she was hospitalized for exacerbation on 28 Oct 2020.'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 20:04:28

US3092043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 20:04:28

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:05:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:55
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 18:33:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:16:49
Data point term sent to Coder Coding entries removed.	System Marissa Cervenka (b) (4)	18 Nov 2020 22:16:41 18 Nov 2020 22:15:51
Coding entries removed.	Marissa Cervenka (b) (4)	18 Nov 2020 22:15:51
User entered 'AMLODIPINE' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 22:15:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: ROFLUMILAST, PRODUCTSYNONYM: DALIRESP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 18:38:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 18:38:17
Data point term sent to Coder User entered 'DALIRESP'	System Shraddha Dubal (b) (4)	17 Aug 2020 18:37:54 17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'HYPERTENSION' reason for change:	(b) (4)	
Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 22:15:51
User entered 'COPD'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:37:08
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '5' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 22:15:51
User entered '500'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:37:08
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Please review if Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:24
' (Site from DM).		
User entered 'mg (mg)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:15:51
Query 'Per DM CLR: Please review if Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate.	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:07:16
' answered with 'done' (Site from DM).		
User entered 'ug (ug)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:07:06
User opened query 'Per DM CLR: Please review if Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate.	(b) (4), (b) (6)	03 Sep 2020 08:26:48
' (Site from DM).		
User entered 'Other (OTHER)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per CDM: Please note that ug (for microgram) is one of the available options for Dose unit from the dropdown list provided. Kindly update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:25:09
Query 'Per CDM: Please note that ug (for microgram) is one of the available options for Dose unit from the dropdown list provided. Kindly update as appropriate. ' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:07:31
User entered empty; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 21:07:06
User opened query 'Per CDM: Please note that ug (for microgram) is one of the available options for Dose unit from the dropdown list provided. Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:25:47
User entered 'MCG'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	18 Nov 2020 21:07:06
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	17 Aug 2020 18:37:08
User entered 'once daily (QD)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty; reason for change Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 21:07:06
User entered 'AM'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:37:08
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (ORAL)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UN UNK 2006' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:15:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:41:41
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 18:37:08
User entered 'UN Dec 2019'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 21:07:06
User entered 'Yes (Y)'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:37:08
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4)	
User entered '07 Sep 2020' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 22:15:51
User entered empty.	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 21:07:06
	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:37:08
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User entered '1'	System	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User entered '1'	System	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:11
User entered '804 (804)'	System	17 Aug 2020 18:37:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.	(b) (4)	06 Apr 2021 16:22:49
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Nov 2020 06:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:38:51
Data point term sent to Coder	System	18 Nov 2020 22:18:46
Coding entries removed.	Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
Coding entries removed.	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
User entered 'PREDISONE' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:17:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 01:05:16
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 01:05:16
Data point term sent to Coder	System	17 Aug 2020 18:52:44
Data point term sent to Coder	System	17 Aug 2020 18:51:40
User entered 'montelukast'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:22:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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	17 Aug 2020 18:52:27
User entered 'No (N)' reason for change: Data Entry Error	System	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
User entered empty.	(b) (4)	
	System	17 Aug 2020 18:50:54
	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:22:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'ASTHMA/COPD EXACERBATION' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'mid seasonal allergies' reason for change: Data Entry Error	System	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:52:27
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
	(b) (4)	
	System	17 Aug 2020 18:50:54
	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.	(b) (4)	06 Apr 2021 16:22:55
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:08:53
Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'medication was entered based on source/subject informed us ' (Site from DM).	destiny robinson (b) (4) (b) (4)	03 Feb 2021 20:37:01
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 17:54:59
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:52:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 18:52:27
User entered '10' reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:50:54
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:22:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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	17 Aug 2020 18:52:27
User entered 'mg (mg)' reason for change: Data Entry Error	System	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
User entered empty.	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:22:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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	17 Aug 2020 18:52:27
User entered 'once daily (QD)' reason for change: Data Entry Error	System	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
User entered empty.	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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	17 Aug 2020 18:52:27
User entered 'Oral (ORAL)' reason for change: Data Entry Error	System	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:14
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.	(b) (4)	06 Apr 2021 16:23:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4)	10 Feb 2021 14:08:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'corrected per query including source ' (Site from DM).	destiny robinson (b) (4)	03 Feb 2021 20:38:46
User entered '2 Oct 2020' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 20:38:33
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 17:55:13
User entered '1 Oct 2020' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Oct 2020 18:10:40
User entered 'Un UNK 2019' reason for change: Data Entry Error	Robert Miranda (b) (4)	17 Oct 2020 18:10:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 18:52:27
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Aug 2020 18:52:27
User entered 'uk UNK 2019' (non-conformant).	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Aug 2020 18:50:54
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:39
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:52:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 18:52:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:50:54
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '9 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
DataPoint Verified.		06 Apr 2021 16:23:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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)	04 Jan 2021 12:00:42
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 AND CORRECTED ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:43:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:43:46
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 03:22:18

PRODUCTION RELEASE (v12.003
EAB) (1725)

2034 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 22:17:50
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:52:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 18:52:27
User entered 'No (N)' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	17 Aug 2020 18:52:27
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:50:54
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
User entered '1'	System	17 Aug 2020 18:52:27
User entered empty.	System	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
User entered '1'	System	17 Aug 2020 18:52:27
User entered empty.	System	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:16
User entered '804 (804)'	System	17 Aug 2020 18:52:27
User entered empty.	System	17 Aug 2020 18:50:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:49
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: OMALIZUMAB, PRODUCTSYNONYM: XOLAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:22:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:22:49
Data point term sent to Coder User entered 'XOLAIR'	System Marissa Cervenka (b) (4)	18 Nov 2020 22:21:48 18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 12:01:39
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:42:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:42:41
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		16 Dec 2020 03:27:11
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'ASTHMA/CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNKNOWN'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Other (OTHER)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNKNOWN'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'other (OTHER)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:29:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'EVERY 2 WEEKS'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:29:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Subcutaneous (SUBCUTANEOUS)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:29:39
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:29:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:09:50
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'Per source this medication is not indicated as related to an AE. This medication was started before Exacerbation of COPD/Asthma AE' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 18:51:45
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 17:56:55
User entered '23 Sep 2020'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:29:54
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:30:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:30:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:30:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 22:21:35

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 19:00:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 19:00:50
Data point term sent to Coder	System	04 Feb 2021 19:00:33
Coding entries removed.	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 18:59:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:24:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:24:52
Data point term sent to Coder	System	18 Nov 2020 22:23:52
User entered 'MUCINEX'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'ASTHMA/COPD' reason for change:	(b) (4)	
Data Entry Error	Heather Jimenez (b) (4)	04 Feb 2021 18:59:51
User entered 'ASTHMA/COPD EXACERBATION'	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '600'	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'mg (mg)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'twice daily (BID)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12 Nov 2020'	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AEs 1, 2 ASTHMA/COPD EXACERBATION (2 OCT 2020 - 10 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 12:30:36
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) (6)	09 Feb 2021 13:57:14
Query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AEs 1, 2 ASTHMA/COPD EXACERBATION (2 OCT 2020 - 10 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' answered with 'Per source indication does not include Exacerbation of medical condition' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 19:02:24
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 'Per source stop date was 19Nov2020- form updated ' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 18:59:35
User entered 'No (N)' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 18:59:27
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)	31 Jan 2021 17:58:20

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AEs 1, 2 ASTHMA/COPD EXACERBATION (2 OCT 2020 - 10 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Dec 2020 03:21:51
	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Jimenez (b) (4)	04 Feb 2021 18:59:27
User entered empty.	(b) (4)	
	Marissa Cervenka (b) (4)	18 Nov 2020 22:22:54
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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)	04 Jan 2021 12:00:27
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 AND CORRECTED ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:44:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:44:40
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 03:20:53
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User entered '2'	System	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User entered '1'	System	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:22
User entered '804 (804)'	System	18 Nov 2020 22:22:54

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:13
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON PERLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:39:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:39:00
Data point term sent to Coder	System	18 Nov 2020 22:25:54
User entered 'TESSALON PERLES'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:15
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:17
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'COUGH DUE TO ASTHMA/COPD EXACERBATION'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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)	10 Feb 2021 12:39:05
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 'Per source notes, actual dose not provided.' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:16:04
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 02:30:59
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:23
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 02:30:56
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 02:30:47
User entered 'capsule (CAPSULE)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:26
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'as needed (PRN)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:34
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12 Nov 2020'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:39
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AEs 1, 2 ASTHMA/COPD EXACERBATION (2 OCT 2020 - 10 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 12:40:06
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) (6)	09 Feb 2021 13:58:35
Query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AEs 1, 2 ASTHMA/COPD EXACERBATION (2 OCT 2020 - 10 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' answered with 'Cough is recorded as due to exacerbated event- no additional AE required' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:24:11
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 'Subject takes medication as needed, stop date not applicable at this time' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:22:24
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)	31 Jan 2021 18:00:25

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AEs 1, 2 ASTHMA/COPD EXACERBATION (2 OCT 2020 - 10 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Dec 2020 03:26:35
	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:44
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:46
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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)	04 Jan 2021 12:01:02
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 AND CORRECTED ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:45:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:45:36
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 03:26:24
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 22:25:44

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.	(b) (4)	06 Apr 2021 16:31:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 03:43:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:43:06
Data point term sent to Coder	System	18 Nov 2020 22:30:58
User entered 'PREDNISONE'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:31:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:15
DataPoint Un-verified.		06 Apr 2021 16:32:13
DataPoint Verified.		06 Apr 2021 16:32:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'ASTHMA/COPD EXACERBATION'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:17
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '20'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:20
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'mg (mg)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:22
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:23
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'once daily (QD)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:27
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:49
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (ORAL)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:56
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '4 Nov 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:32:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:33:00
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:33:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12 Nov 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
DataPoint Verified.		06 Apr 2021 16:33:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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). 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 AND CORRECTED ' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Jan 2021 12:01:11
	(b) (4), (b) (6)	30 Dec 2020 17:46:32
	(b) (4), (b) (6)	30 Dec 2020 17:46:24

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	16 Dec 2020 03:24:41
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
User entered '1'	System	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
User entered '1'	System	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:27
User entered '804 (804)'	System	18 Nov 2020 22:30:21

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:33:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:06:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:06:43
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:28:10
Data point term sent to Coder	System	06 Feb 2021 00:27:25
Data point term sent to Coder	System	06 Feb 2021 00:25:18
Coding entries removed.	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:24:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 03:42:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 03:42:06
Data point term sent to Coder	System	24 Nov 2020 22:23:41
User closed query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	System	24 Nov 2020 22:23:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

2114 of 2365

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'Updated.' (Site from System).	Catina Adams (b) (4)	24 Nov 2020 22:23:07
User entered 'PROTONIX (pantoprazole)' reason for change: Data Entry Error	Catina Adams (b) (4)	24 Nov 2020 22:22:57
User opened query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 08:40:07
Data point term sent to Coder	System	18 Nov 2020 22:32:00
User entered 'PROTONIX'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:33:15
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:33:17
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:59:42
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Medication was prescribed for cough related to exacerbated event' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:28:21
User entered 'COUGH due to exacerbated event' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:26:52
User entered 'Cough' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:24:52
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:25:55
User entered 'ASTHMA/COPD EXACERBATION'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:33:23
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 12:38:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Per source notes, actual dose and unit not provided' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	06 Feb 2021 00:28:14
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:26:02
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'tablet (TABLET)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:34
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'once daily (QD)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:39
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:43
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:47
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '12 Nov 2020'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:49
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:56
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
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)	09 Feb 2021 14:01:00
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' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 19:24:35
User entered 'No (N)' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 19:24:22
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).	(b) (4), (b) (6)	16 Dec 2020 03:25:28
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 22:31:31

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: ROFLUMILAST, PRODUCTSYNONYM: DALIRESP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:49:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:49:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: ROFLUMILAST, PRODUCTSYNONYM: DALIRESP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:34:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 22:34:49
Data point term sent to Coder User entered 'DALIRESP'	System Marissa Cervenka (b) (4)	18 Nov 2020 22:34:01 18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '500'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'ug (ug)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'once daily (QD)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UN Dec 2019'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '7 Sep 2020'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User entered '1'	System	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User entered '1'	System	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:32
User entered '804 (804)'	System	18 Nov 2020 22:33:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Nov 2020 03:52:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:52:58
Data point term sent to Coder	System	18 Nov 2020 22:40:04
User entered 'MONTELUKAST'	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:39:15

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'MID SEASONAL ALLERGIC RHINITIS'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '10'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'mg (mg)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'once daily (QD)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'UN UNK 2019'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 22:39:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 22:39:32
User entered 'No (N)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 22:39:15
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:39:15
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:39:15

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:39:15

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 22:39:15

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Nov 2020 22:42:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:42:54
Data point term sent to Coder User entered 'LOSARTAN'	System Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:42:05 18 Nov 2020 22:41:13

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'HYPERTENSION'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'UNKNOWN'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'Other (OTHER)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'UNKNOWN'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'once daily (QD)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'UN Oct 2020'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:41:13
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:41:13

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:41:13

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 22:41:13

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS A VACCINE;HEPATITIS B VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 04:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:25:53
Data point term sent to Coder	System	18 Nov 2020 22:45:13
User entered 'HEPATITIS A & B '	Marissa Cervenka (b) (4) (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'PROPHYLAXIS HEPATITIS A & B'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNKNOWN'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Other (OTHER)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNKNOWN'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'once (ONCE)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '1 Oct 2020'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '1 Oct 2020'	(b) (4) Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	Marissa Cervenka (b) (4)	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User entered empty.	System	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User entered empty.	System	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:58
User entered empty.	System	18 Nov 2020 22:44:40

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:18:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:18:35
Data point term sent to Coder	System	27 Feb 2021 20:59:16
Coding entries removed.	(b) (4), (b) (6)	27 Feb 2021 20:59:04
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:04:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:04:20
Data point term sent to Coder	System	28 Jan 2021 18:03:09
Coding entries removed.	(b) (4), (b) (6)	28 Jan 2021 18:02:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:56:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:56:54
Data point term sent to Coder	System	07 Dec 2020 16:17:52
User entered 'SHINGLES vaccination'	(b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 20:59:04
User entered 'PROPHYLAXIS SHINGLES' reason for change: Data Entry Error		27 Feb 2021 20:59:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'prophylaxis'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'unk'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 07:29:57
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'CORRECTION MADE ' (Site from DM).		28 Jan 2021 18:02:25
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error		28 Jan 2021 18:02:17
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).		28 Jan 2021 03:15:07
User entered 'Oral (ORAL)'		07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:29:27
User entered 'Yes (Y)'		07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:29:27
User entered empty.		07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User entered empty.	System	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User entered empty.	System	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:02
User entered empty.	System	07 Dec 2020 16:17:08

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:26:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:26:46
Data point term sent to Coder	System	27 Feb 2021 21:00:16
Coding entries removed.	(b) (4), (b) (6)	27 Feb 2021 20:59:48
User signature succeeded.	Valentine Ebu (b) (4) (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:42:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:42:48
Data point term sent to Coder	System	28 Jan 2021 18:03:09
Coding entries removed.	(b) (4), (b) (6)	28 Jan 2021 18:03:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:36:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:36:48
Data point term sent to Coder	System	07 Dec 2020 16:19:53
User entered 'tetanus vaccination'	(b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 20:59:48
User entered 'PROPHYLAXIS TETANUS' reason for change: Data Entry Error		27 Feb 2021 20:59:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'prophylaxis'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'unk'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 07:30:14
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'CORRECTION MADE ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:03:14
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error		28 Jan 2021 18:03:06
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).		28 Jan 2021 03:18:24
User entered 'Oral (ORAL)'		07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:29:43
User entered 'Yes (Y)' reason for change: Data Entry Error		07 Dec 2020 16:19:20
User entered 'No (N)'		07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:29:43
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	07 Dec 2020 16:19:20
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	07 Dec 2020 16:19:11
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User entered empty.	System	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User entered empty.	System	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:06
User entered empty.	System	07 Dec 2020 16:19:11

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 21:01:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 21:01:54
Data point term sent to Coder	System	27 Feb 2021 21:01:17
Coding entries removed.	(b) (4), (b) (6)	27 Feb 2021 21:00:45
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:28:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 16:23:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 16:23:49
Data point term sent to Coder	System	07 Dec 2020 16:22:55
User entered 'FLU SHOT'	(b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 21:00:45
User entered 'PROPHYLAXIS INFLUENZA' reason for change: Data Entry Error		27 Feb 2021 21:00:45
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'INFLUENZA VACCINE'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	07 Dec 2020 16:23:03
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 16:23:03
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	07 Dec 2020 16:22:53
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User entered empty.	System	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User entered empty.	System	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:10
User entered empty.	System	07 Dec 2020 16:22:53

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 15:23:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 15:23:37
Data point term sent to Coder	System	28 Apr 2021 14:54:07
User entered 'Hydrocodone/Acetaminophen'	Catina Adams (b) (4)	28 Apr 2021 14:53:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'Back Pain Surgery'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered '10/325'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'other (OTHER)'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'PRN every 6 hours'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'Oral (ORAL)'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered '09 Apr 2021'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'Yes (Y)'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:00
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	28 Apr 2021 14:53:48
	(b) (4)	

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 14:53:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 14:53:48

US3092043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:05:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 14:53:48

US3092043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:05:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 20:52:56

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'USA-US086-2020-MRNA-1273-P301000005'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Valentine'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Ebuh'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Un-reviewed for Safety.	(b) (4)	
System		11 Feb 2021 16:11:18
User entered '2701 S Hampton Road, Suite 250'	System	11 Feb 2021 16:11:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '2701 S. Hampton Rd., Suite 250'	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	25 Nov 2020 20:25:26
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
User entered '2701 S. Hampton Road' reason for change: Data Entry Error	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
(b) (4), (b) (6)		19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:29
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered 'Dallas' reason for change: Data Entry Error	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
Un-reviewed for Safety.	System	25 Nov 2020 20:25:26
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'TX'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	18 Feb 2021 17:22:23
User entered (b) (6)	(b) (4)	
(non-conformant).	System	11 Feb 2021 16:11:18
Reviewed for Safety.	System	11 Feb 2021 16:11:18
	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
DataPoint Un-verified.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
(non-conformant).	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
DataPoint Verified.		24 Nov 2020 23:42:30
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04
(non-conformant).		

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:04:44
DataPoint Verified.		19 Nov 2020 17:07:17
User entered 'US'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '4'	System	11 Feb 2021 16:11:18
User entered '3'	System	25 Nov 2020 20:25:26
User entered '2'	System	22 Nov 2020 16:05:10
User entered '1'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'USA-US086-2020-MRNA-1273-P301000005'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Valentine'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Ebuh'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Un-reviewed for Safety.	(b) (4)	
System		11 Feb 2021 16:11:18
User entered '2701 S Hampton Road, Suite 250'	System	11 Feb 2021 16:11:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '2701 S. Hampton Rd., Suite 250'	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	25 Nov 2020 20:25:26
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
User entered '2701 S. Hampton Road' reason for change: Data Entry Error	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:29
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered 'Dallas' reason for change: Data Entry Error	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'TX'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	18 Feb 2021 17:22:23
User entered (b) (6)	(b) (4)	
(non-conformant).	System	11 Feb 2021 16:11:18
Reviewed for Safety.	System	11 Feb 2021 16:11:18
	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
DataPoint Un-verified.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
(non-conformant).	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
DataPoint Verified.		24 Nov 2020 23:42:30
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04
(non-conformant).		

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:04:44
DataPoint Verified.		19 Nov 2020 17:07:17
User entered 'US'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '4'	System	11 Feb 2021 16:11:18
User entered '3'	System	25 Nov 2020 20:25:26
User entered '2'	System	22 Nov 2020 16:05:10
User entered '1'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
User entered '19/Nov/2020 13:30'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:05:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:04:44
DataPoint Verified.		19 Nov 2020 17:07:17
User entered 'I'		19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'USA-US086-2020-MRNA-1273-P301000005'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Valentine'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Ebuh'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Un-reviewed for Safety.	(b) (4)	
System		11 Feb 2021 16:11:18
User entered '2701 S Hampton Road, Suite 250'	System	11 Feb 2021 16:11:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '2701 S. Hampton Rd., Suite 250'	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	25 Nov 2020 20:25:26
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
User entered '2701 S. Hampton Road' reason for change: Data Entry Error	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
(b) (4), (b) (6)		19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:29
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered 'Dallas' reason for change: Data Entry Error	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'TX'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	18 Feb 2021 17:22:23
User entered (b) (6)	(b) (4)	
(non-conformant).	System	11 Feb 2021 16:11:18
Reviewed for Safety.	System	11 Feb 2021 16:11:18
	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
DataPoint Un-verified.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
(non-conformant).	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
DataPoint Verified.		24 Nov 2020 23:42:30
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04
(non-conformant).		

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:04:44
DataPoint Verified.		19 Nov 2020 17:07:17
User entered 'US'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '4'	System	11 Feb 2021 16:11:18
User entered '3'	System	25 Nov 2020 20:25:26
User entered '2'	System	22 Nov 2020 16:05:10
User entered '1'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:59:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '22/Nov/2020 11:05'	(b) (4) System	22 Nov 2020 16:05:10

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:05:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:59:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:25:14
User entered 'I'		22 Nov 2020 16:05:10

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'USA-US086-2020-MRNA-1273-P301000005'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Valentine'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Ebuh'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Un-reviewed for Safety.	(b) (4)	
System		11 Feb 2021 16:11:18
User entered '2701 S Hampton Road, Suite 250'	System	11 Feb 2021 16:11:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '2701 S. Hampton Rd., Suite 250'	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	25 Nov 2020 20:25:26
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
User entered '2701 S. Hampton Road' reason for change: Data Entry Error	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:29
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered 'Dallas' reason for change: Data Entry Error	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'TX'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	18 Feb 2021 17:22:23
User entered (b) (6)	(b) (4)	
(non-conformant).	System	11 Feb 2021 16:11:18
Reviewed for Safety.	System	11 Feb 2021 16:11:18
	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
DataPoint Un-verified.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
(non-conformant).	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
DataPoint Verified.		24 Nov 2020 23:42:30
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04
(non-conformant).		

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:04:44
DataPoint Verified.		19 Nov 2020 17:07:17
User entered 'US'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '4'	System	11 Feb 2021 16:11:18
User entered '3'	System	25 Nov 2020 20:25:26
User entered '2'	System	22 Nov 2020 16:05:10
User entered '1'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:59:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '25/Nov/2020 15:25'	(b) (4) System	25 Nov 2020 20:25:26

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:05:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:59:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered 'I'		25 Nov 2020 20:25:26

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'USA-US086-2020-MRNA-1273-P301000005'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Yes (Y)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'No (N)'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Valentine'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'Ebuh'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Un-reviewed for Safety.	(b) (4)	
System		11 Feb 2021 16:11:18
User entered '2701 S Hampton Road, Suite 250'	System	11 Feb 2021 16:11:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '2701 S. Hampton Rd., Suite 250'	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	25 Nov 2020 20:25:26
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
Robert Miranda (b) (4)		23 Nov 2020 21:54:54
User entered '2701 S. Hampton Road' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 17:07:17
User entered (b) (6)	System	19 Nov 2020 13:30:07
		19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:29
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered 'Dallas' reason for change: Data Entry Error	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
Un-reviewed for Safety.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Un-verified.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered 'TX'	System	19 Nov 2020 13:29:04

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	18 Feb 2021 17:22:23
User entered (b) (6)	(b) (4)	
(non-conformant).	System	11 Feb 2021 16:11:18
Reviewed for Safety.	System	11 Feb 2021 16:11:18
	(b) (4), (b) (6)	11 Feb 2021 16:11:07
User entered '75224' reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	Vicki Martinez (b) (4)	07 Dec 2020 20:10:09
DataPoint Un-verified.	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 20:25:26
(non-conformant).	System	25 Nov 2020 20:25:26
Reviewed for Safety.	System	25 Nov 2020 20:25:26
	(b) (4), (b) (6)	25 Nov 2020 20:25:14
DataPoint Verified.		24 Nov 2020 23:42:30
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:54:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:07:17
Reviewed for Safety.		19 Nov 2020 13:30:07
User entered (b) (6)	System	19 Nov 2020 13:29:04
(non-conformant).		

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 16:04:44
DataPoint Verified.		19 Nov 2020 17:07:17
User entered 'US'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
	(b) (4)	
User entered '4'	System	11 Feb 2021 16:11:18
User entered '3'	System	25 Nov 2020 20:25:26
User entered '2'	System	22 Nov 2020 16:05:10
User entered '1'	System	19 Nov 2020 13:30:23

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:05:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:59:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered '11/Feb/2021 10:11'	(b) (4) System	11 Feb 2021 16:11:18

US3092043

Folder: SAE USA-US086-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:05:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:59:42
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:11:18