

US3092176 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:08:16

All time stamps listed in this document are displayed in GMT

US3092176

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

[Participant ID](#)

US3092176

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

US3092176

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

Visit date (dd MMM yyyy)	20 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3092176

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	47
Age Units	YEARS
Age (Derived)	47
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3092176

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3092176

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3092176

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Were any significant conditions reported?

Yes ☒

No ☐

US3092176

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3092176

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	DMT2
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3092176

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	ADENOID REMOVAL
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

US3092176

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	RIGHT FOOT FRACTURE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3092176

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	TENDON TEAR RIGHT HAND
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3092176

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	ARTHROSCOPY ON LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3092176

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	C4-6 FUSE SURGERY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3092176

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	ADHD
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3092176

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	ASTHMA MILD
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	
Stop Year (derived)	

US3092176

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN (b) (6) 1973
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)	(b) (6) 1973
Start Year (derived)	1973
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3092176

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	LEFT KNEE TORN MENISCUS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3092176

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Condition	LEFT KNEE TORN MENISCUS REPAIR
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3092176

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 22:47:41

Generated On: 09 Jun 2021 15:08:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:18 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:18
Height (<i>xxx.x</i>)	190.5 cm
Weight (<i>xxx.x</i>)	117.3 kg
BMI (<i>xxx.x</i>)	32.32273 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)	

US3092176

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3092176

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

Visit date (dd MMM yyyy)	20 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3092176

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 144552

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Height	ND - Not Done
Weight	ND - Not Done

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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)	20 AUG 2020
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:18
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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)	20 AUG 2020
Time of assessment (00:00-23:59)	16:22 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:22
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 15:34 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 15:34

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

US3092176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	14:38 (24 HR)
Collection date and time (derived)	20 AUG 2020 14:38

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:35	20 AUG 2020 14:35
Nasopharyngeal Swab 2	No		

US3092176

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

98.3 °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

20 AUG 2020 16:20

PC Open Date & Time

20 AUG 2020 15:54

PC Close Date & Time

20 AUG 2020 18:24

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	21 AUG 2020 08:40
PC Open Date & Time	20 AUG 2020 19:19
PC Close Date & Time	21 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 11:32

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 07:19

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

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 98.3 °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):

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

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

PC Time Stamp 24 AUG 2020 21:18

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

25 AUG 2020 12:52

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 16:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

20 AUG 2020 16:20

PC Open Date & Time

20 AUG 2020 15:54

PC Close Date & Time

20 AUG 2020 18:24

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

21 AUG 2020 08:39

PC Open Date & Time

20 AUG 2020 19:19

PC Close Date & Time

21 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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)**

10

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

22 AUG 2020 11:35

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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 - **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

23 AUG 2020 07:19

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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)**

4

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

24 AUG 2020 21:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

25 AUG 2020 12:52

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

26 AUG 2020 16:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 16:21
PC Open Date & Time	20 AUG 2020 15:54
PC Close Date & Time	20 AUG 2020 18:24

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 08:40
PC Open Date & Time	20 AUG 2020 19:19
PC Close Date & Time	21 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

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 ☒

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 11:35
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

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)

56 of 2387

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 07:19
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

Yes ☐

PC Time stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

60 of 2387

EAB) (1725)

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 21:19
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

62 of 2387

EAB) (1725)

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:53
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

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 ☒

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 16:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3092176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 16:38:07

Generated On: 09 Jun 2021 15:08:16

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

CALL WAS NOT ATTEMPTED,
CALL WAS MISSED

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

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)	18 SEP 2020
Time of assessment (00:00-23:59)	10:39 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:39
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

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)	18 SEP 2020
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:37
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 11:05 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 11:05

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

US3092176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

11:02 (24 HR)

Collection date and time (derived)

18 SEP 2020 11:02

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:58	18 SEP 2020 10:58
Nasopharyngeal Swab 2	No		

US3092176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

98.9 °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

18 SEP 2020 11:35

PC Open Date & Time

18 SEP 2020 11:25

PC Close Date & Time

18 SEP 2020 13:55

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	18 SEP 2020 16:42
PC Open Date & Time	18 SEP 2020 14:50
PC Close Date & Time	19 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

19 SEP 2020 20:48

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	20 SEP 2020 15:48
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 SEP 2020 18:03

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	23 SEP 2020 00:00
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 SEP 2020 13:04

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

97.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

25 SEP 2020 01:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 8

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 9

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

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

18 SEP 2020 11:35

PC Open Date & Time

18 SEP 2020 11:25

PC Close Date & Time

18 SEP 2020 13:55

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

7

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)**

4

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

18 SEP 2020 16:43

PC Open Date & Time

18 SEP 2020 14:50

PC Close Date & Time

19 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

19 SEP 2020 20:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

20 SEP 2020 15:50

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

21 SEP 2020 18:04

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

23 SEP 2020 00:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

23 SEP 2020 13:04

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

25 SEP 2020 01:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 11:35
PC Open Date & Time	18 SEP 2020 11:25
PC Close Date & Time	18 SEP 2020 13:55

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 16:43
PC Open Date & Time	18 SEP 2020 14:50
PC Close Date & Time	19 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

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 ☒

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 20:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

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 ☒

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 15:51
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

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 ☒

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 18:05
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

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
EAB) (1725)

109 of 2387

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 00:01
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

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 ☒

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 13:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

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)

113 of 2387

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 01:45
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3092176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 10:55
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3092176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

11:05 (24 HR)

Collection date and time (derived)

16 OCT 2020 11:05

US3092176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:04

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 18:58:37

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 06:08:09

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 103

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐ 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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	09 DEC 2020 23:59
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US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

12 DEC 2020 05:29:06

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

23 DEC 2020 10:34:14

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

26 DEC 2020 05:13:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

02 JAN 2021 08:36:23

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

11 JAN 2021 11:37:08

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

16 JAN 2021 02:54:04

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

23 JAN 2021 09:11:08

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 15:21:03

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

06 FEB 2021 09:21:07

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 FEB 2021 05:30:12
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

22 FEB 2021 16:09:03

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 00:07:50

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

08 MAR 2021 18:56:13

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

16 MAR 2021 22:26:11

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

21 MAR 2021 11:22:40

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

29 MAR 2021 18:59:23

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 APR 2021 09:40:55
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 APR 2021 14:16:24
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

19 APR 2021 17:19:44

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

24 APR 2021 07:25:58

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

01 MAY 2021 00:17:50

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐
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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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"/>

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐ 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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 334

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

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

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

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

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

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

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐
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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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"/>

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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"/>

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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°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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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°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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐
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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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="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"/>

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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°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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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"/>

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐
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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐ 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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐ 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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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°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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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 ☐
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 ☐

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3092176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:08:16

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		27 FEB 2021 10:54:20

US3092176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 16:38:07

Generated On: 09 Jun 2021 15:08:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 10:35
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)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3092176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 16:38:07

Generated On: 09 Jun 2021 15:08:16

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

Collection date (dd MMM yyyy)	22 MAR 2021
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Collection time (00:00-23:59)	10:50 (24 HR)
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Collection date and time (derived)	22 MAR 2021 10:50
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US3092176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092176

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:08:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3092176

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3092176

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

Form: Unblinding

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 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

US3092176

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Height	190.5 cm
Weight	277.2 lb
BMI (xxx.x)	34.72007

US3092176

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Height	190.5 cm
Weight	277.2 lb
BMI (xxx.x)	34.72007
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)	14 JAN 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Height	190.5 cm
Weight	277.2 lb
BMI (xxx.x)	34.72007
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)	14 JAN 2021
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 12:02
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3092176

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 11:29

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

US3092176

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

11:26 (24 HR)

Collection date and time (derived)

14 JAN 2021 11:26

US3092176

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

Collection date (dd MMM yyyy)	14 JAN 2021
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Collection time (00:00 - 23:59)	11:24
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Collection Date and Time (derived)	14 JAN 2021 11:24
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US3092176

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Mar 2021 18:27:32

Generated On: 09 Jun 2021 15:08:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Mar 2021 18:27:32

Generated On: 09 Jun 2021 15:08:16

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:15
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Mar 2021 18:27:32

Generated On: 09 Jun 2021 15:08:16

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 12:13
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3092176

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Mar 2021 18:27:32

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3092176

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Mar 2021 18:27:32

Generated On: 09 Jun 2021 15:08:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 11:43 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 11:43

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

US3092176

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:27:32

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 22:47:41

Generated On: 09 Jun 2021 15:08:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 22:47:41

Generated On: 09 Jun 2021 15:08:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092176

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:35 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 10:35
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	102 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092176

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3092176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Mar 2021 01:03:40

Generated On: 09 Jun 2021 15:08:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	22 MAR 2021 10:50

US3092176

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Apr 2021 01:01:37

Generated On: 09 Jun 2021 15:08:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

AEID	USA-US086-2021-MRNA-1273-P30 1000015
Adverse event	PANCREATITIS
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)	30 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	10 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2387

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 03:54:03

Generated On: 09 Jun 2021 15:08:16

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

Yes ☒

No ☐

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

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication FLU SHOT

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS INFLUENZA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

364 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)		06 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 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"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication FEVER(SOLICITED AE)

Dose per administration 800

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

366 of 2387

EAB) (1725)

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 AUG 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication SPINAL STENOSIS

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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 2017	
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"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 40

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)

372 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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 2015
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"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration UNK

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)

374 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETIES

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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 FEB 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication ZYRTEC (CETIRIZINE)

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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 UNK 2000	
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"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication CALCIUM/MAGNESIUM/ZINC

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration UNK

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)

380 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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 FEB 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"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 29

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)

382 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	1 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication CLYINDOMYOCIN

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

Dose per administration 150

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)

384 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	1 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

386 of 2387

EAB) (1725)

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	1 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

388 of 2387

EAB) (1725)

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	1 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication METHOCARBOMAL

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

390 of 2387

EAB) (1725)

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	1 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

Name of Medication DICLYCOMINE

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2387

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:22:57

Generated On: 09 Jun 2021 15:08:16

	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)	1 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Mar 2021 18:27:31

Generated On: 09 Jun 2021 15:08:16

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3092176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:08:16

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

US3092176

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:08:16

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 ☐

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

SAEID	USA-US086-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

SAEID	USA-US086-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 14:11
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

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

SAEID	USA-US086-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 10:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

SAEID	USA-US086-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 15:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 02:22:58

Generated On: 09 Jun 2021 15:08:16

SAEID	USA-US086-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 12:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3092176 (Prod: Global Medical Research - M3 Wake Research)

US3092176

Form: Participant Creation

Generated On: 09 Jun 2021 15:08:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'US3092176'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:38

US3092176

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:36:48

US3092176

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:39

US3092176

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Clinic (Clinic)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:36:48

US3092176

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'SCRN'	System	20 Aug 2020 19:36:48

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered (b) (6) 1973'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:40

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '47'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'YEARS'	System	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '47'	System	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Male (M)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'I'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:37:43

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Aug 2020'	System	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2020'	System	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Amendment 2 (2)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:23

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:39

US3092176

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'I'	System	20 Aug 2020 19:39:43

US3092176

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:39:43

US3092176

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:08:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:45:25

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:03:19
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Medication added.' (Site from DM).	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:19:25
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:40:54
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:48:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:48:47
Data point term sent to Coder	System	16 Nov 2020 20:47:45
User entered 'hypertension'	(b) (4), (b) (6)	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2019'	System	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2019'	System	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:46:57

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:03:39
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Medication added' (Site from DM).	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:19:52
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:41:18
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:48:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:48:47
Data point term sent to Coder	System	16 Nov 2020 20:47:41
User entered 'DMT2'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN Feb 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Feb 2020'	System	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2020'	System	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:47:26

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenoidectomy, LLT: Adenoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:49:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:49:52
Data point term sent to Coder	System	16 Nov 2020 20:48:46
User entered 'ADENOID REMOVAL'	(b) (4), (b) (6)	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 1978'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 1978'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 1978'	System	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '1978'	System	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 1978'	System	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '1978'	System	16 Nov 2020 20:48:10

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:49:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:49:51
Data point term sent to Coder	System	16 Nov 2020 20:48:46
User entered 'RIGHT FOOT FRACTURE'	(b) (4), (b) (6)	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2001'	System	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2001'	System	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2001'	System	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2001'	System	16 Nov 2020 20:48:41

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Tendon rupture - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 03:30:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 03:30:51
Data point term sent to Coder	System	16 Nov 2020 20:49:50
User entered 'TENDON TEAR RIGHT HAND'	(b) (4), (b) (6)	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2012'	System	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2012'	System	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2012'	System	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2012'	System	16 Nov 2020 20:49:23

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User closed query 'Per CDM, DM CLR re-query: Please note that the associated condition (MH#12) started and ended on UN UNK 2005, whereas the date of this procedure is recorded for UN UNK 2015. Please review if dates need to be reconciled, else clarify. ' (Site from DM). User signature succeeded.	(b) (4)	14 Apr 2021 06:53:10
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\23.0.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	13 Apr 2021 13:45:19
Query 'Per CDM, DM CLR re-query: Please note that the associated condition (MH#12) started and ended on UN UNK 2005, whereas the date of this procedure is recorded for UN UNK 2015. Please review if dates need to be reconciled, else clarify. ' answered with 'Condition name updated to reflect that no surgical operation was done at this time. The arthroscopy was simply done as an exploratory diagnostic procedure to monitor the long-term post-surgical status of the left knee torn meniscus repair (UN UNK 2005) which was done to address the underlying medical condition of the left knee torn meniscus (UN UNNK 2005).' (Site from DM).	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:45:19
Data point term sent to Coder Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 21:19:08
User entered 'ARTHROSCOPY ON LEFT KNEE' reason for change: Data Entry Error	System	12 Apr 2021 21:08:47
User opened query 'Per CDM, DM CLR re-query: Please note that the associated condition (MH#12) started and ended on UN UNK 2005, whereas the date of this procedure is recorded for UN UNK 2015. Please review if dates need to be reconciled, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 21:08:05
		18 Mar 2021 10:45:22

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
User closed query 'Per CDM, DM CLR re-query: Thank you for the update; however, please ensure the associated condition and the procedure are both captured as separate entries on the MH page. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 10:45:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:24:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Mar 2021 16:24:46
Query 'Per CDM, DM CLR re-query: Thank you for the update; however, please ensure the associated condition and the procedure are both captured as separate entries on the MH page. Review and update as appropriate. ' answered with 'Second entry Left Knee Torn Meniscus' (Site from DM).	Catina Adams (b) (4)	17 Mar 2021 16:24:24
Data point term sent to Coder	System	17 Mar 2021 16:24:04
Coding entries removed.	Catina Adams (b) (4)	17 Mar 2021 16:23:38
User entered 'ARTHROSCOPY SURGERY ON LEFT KNEE' reason for change: Data Entry Error	Catina Adams (b) (4)	17 Mar 2021 16:23:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 09:40:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 09:40:41
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) (6)	10 Feb 2021 09:05:52
User opened query 'Per CDM, DM CLR re-query: Thank you for the update; however, please ensure the associated condition and the procedure are both captured as separate entries on the MH page. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:05:50
Data point term sent to Coder	System	04 Feb 2021 01:24:47

PRODUCTION RELEASE (v12.003
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486 of 2387

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
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' (Site from DM). Coding entries removed.	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:24:17
User entered 'ARTHROSCOPY SURGERY ON LEFT KNEE (Left knee joint pain)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:24:09
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)	07 Jan 2021 16:42:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:25:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:25:03
Data point term sent to Coder	System	16 Nov 2020 20:50:51
User entered 'ARTHROSCOPY SURGERY ON LEFT KNEE'	(b) (4), (b) (6)	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2015'	System	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2015'	System	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2015'	System	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2015'	System	16 Nov 2020 20:50:24

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Nov 2020 07:23:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:23:17
Data point term sent to Coder	System	16 Nov 2020 20:50:55
User entered 'C4-6 FUSE SURGERY'	(b) (4), (b) (6)	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2017'	System	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2017'	System	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2017'	System	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2017'	System	16 Nov 2020 20:50:53

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Psychiatric disorders, HLG: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 20:52:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 20:52:51
Data point term sent to Coder	System	16 Nov 2020 20:51:56
User entered 'ADHD'	(b) (4), (b) (6)	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2010'	System	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2010'	System	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:51:11

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed 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 for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:06:24
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 for no medical treatment. ' answered with 'Medication added' (Site from DM).	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:24:58
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 for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:42:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:52:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:52:49
Data point term sent to Coder	System	16 Nov 2020 20:51:56
User entered 'ASTHMA MILD'	(b) (4), (b) (6)	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 1978'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 1978'	System	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '1978'	System	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:51:37

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Nov 2020 20:55:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:55:49
Data point term sent to Coder	System	16 Nov 2020 20:53:58
User entered 'SPINAL STENOSIS'	(b) (4), (b) (6)	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2016'	System	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2016'	System	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:53:30

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed query 'Per MM, please spell out abbreviation' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 12:05:35
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 18:43:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 18:43:51
Data point term sent to Coder	System	15 Dec 2020 18:42:35
Query 'Per MM, please spell out abbreviation' answered with 'corrected per chart ' (Site from DM).	destiny robinson (b) (4) (b) (4)	15 Dec 2020 18:42:27
Coding entries removed.	destiny robinson (b) (4) (b) (4)	15 Dec 2020 18:42:16
User entered 'seasonal allergic rhinitis' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	15 Dec 2020 18:42:16
User opened query 'Per MM, please spell out abbreviation' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 12:25:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:55:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:55:51
Data point term sent to Coder	System	16 Nov 2020 20:55:00
User entered 'SAR'	(b) (4), (b) (6)	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	16 Nov 2020 21:02:02
User entered 'UN (b) (6) 1973' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:02:02
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	16 Nov 2020 20:54:20
User entered 'UN UNK 1973'	(b) (4), (b) (6)	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered (b) (6) 1973'	System	16 Nov 2020 21:02:02
User entered (b) (6) 1973'	System	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '1973'	System	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered empty.	System	16 Nov 2020 20:54:20

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:24:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 16:24:45
Data point term sent to Coder	System	17 Mar 2021 16:24:05
User entered 'Left Knee Torn Meniscus'	Catina Adams (b) (4)	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2005'	Catina Adams (b) (4)	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	Catina Adams (b) (4)	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	Catina Adams (b) (4)	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2005'	Catina Adams (b) (4)	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	Catina Adams (b) (4)	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2005'	System	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2005'	System	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2005'	System	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2005'	System	17 Mar 2021 16:23:13

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Apr 2021 21:37:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:37:13
Data point term sent to Coder	System	12 Apr 2021 21:21:00
User entered 'LEFT KNEE TORN MENISCUS REPAIR'	(b) (4), (b) (6)	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2005'	System	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2005'	System	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'Jan 2005'	System	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '2005'	System	12 Apr 2021 21:20:06

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '14:18'	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered '20 Aug 2020 14:18'	System	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '190.5' cm	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11
DataPoint set to visible.	(b) (4) System	20 Aug 2020 19:39:43

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '117.3' kg	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11
DataPoint set to visible.	(b) (4) System	20 Aug 2020 19:39:43

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
Amendment Manager: User entered '32.32273'	System	17 Sep 2020 00:16:53
User entered '32.3'	System	22 Aug 2020 23:47:11
DataPoint set to visible.	System	20 Aug 2020 19:39:43

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'kg/m2'	System	22 Aug 2020 23:47:11
DataPoint set to visible.	System	20 Aug 2020 19:39:43

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User closed query 'Per CDM(Requery) : Please note as the route for Measurement should be "Empty" as the Temperature should be "ND" in Screening as the Screening and Visit date on the same day. .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 10:14:24
Query 'Per CDM(Requery) : Please note as the route for Measurement should be "Empty" as the Temperature should be "ND" in Screening as the Screening and Visit date on the same day. .Thanks ' answered with 'updated' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 00:26:37
User entered empty; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 00:26:29
User opened query 'Per CDM(Requery) : Please note as the route for Measurement should be "Empty" as the Temperature should be "ND" in Screening as the Screening and Visit date on the same day. .Thanks ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:41:26
User closed query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:39:44
Query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' answered with 'the answer is ND ' (Site from DM).	destiny robinson (b) (4) (b) (4)	15 Dec 2020 18:38:22
User opened query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 14:04:48
User entered 'Other (Other)'	Marissa Cervenka (b) (4) (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User closed query 'Per CDM re-query: If other, specify has to be empty as temperature is ND. Kindly update accordingly. Thank you.' (Site from DM).	(b) (4)	09 Mar 2021 10:22:06
Query 'Per CDM re-query: If other, specify has to be empty as temperature is ND. Kindly update accordingly. Thank you.' answered with 'confirmed, update made' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:54:50
User entered empty; reason for change Data Entry Error		09 Mar 2021 00:54:27
User opened query 'Per CDM re-query: If other, specify has to be empty as temperature is ND. Kindly update accordingly. Thank you.' (Site from DM).		05 Feb 2021 10:16:12
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11
	(b) (4)	

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'bpm'	System	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'breaths/min'	System	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'mmHg'	System	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User entered 'mmHg'	System	22 Aug 2020 23:47:11

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03

US3092176

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03

US3092176

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:31

US3092176

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:47:31

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'I'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '0'	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:26:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 19:40:48

US3092176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:41:17

US3092176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	20 Aug 2020 19:41:17

US3092176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Clinic (Clinic)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:41:17

US3092176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'VISIT1'	System	20 Aug 2020 19:41:17

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:29:32

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 06:00:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:00:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 19:29:32
User entered '144552' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:29:32

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:29:32

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:42:24

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:42:24

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:42:24

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:42:24

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	20 Aug 2020 19:42:24

US3092176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:50:25

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Pre-Dose (PREDOSE)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36
	(b) (4)	

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14:18'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '20 Aug 2020 14:18'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '97.5' F	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '87'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'bpm'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Oct 2020 15:20:44
Query 'Data is required. Please provide.' answered by System	System	23 Oct 2020 15:20:44
data change (Site from System).		
User entered '17' reason for change: Data Entry Error	Catina Adams (b) (4)	23 Oct 2020 15:20:44
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 23:49:36
User entered empty.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36
	(b) (4)	

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'breaths/min'	System	23 Oct 2020 15:20:44
User entered empty.	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '142'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '93'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Post-Dose (POSTDOSE)'	Marissa Cervenka (b) (4) (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16:22'	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36
	(b) (4)	

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '20 Aug 2020 16:22'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '98' F	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)'	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36
	(b) (4)	

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '81'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'bpm'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'breaths/min'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '140'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '81'	Marissa Cervenka (b) (4)	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	22 Aug 2020 23:49:36

US3092176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:50:22

US3092176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:50:22

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '15:34'	Marissa Cervenka (b) (4)	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '20 Aug 2020 15:34'	System	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Left Arm (LEFT ARM)'	Marissa Cervenka (b) (4)	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'ONCE'	System	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 20:58:34

US3092176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:51:44

US3092176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:51:44

US3092176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14:38'	Marissa Cervenka (b) (4)	22 Aug 2020 23:51:44

US3092176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '20 Aug 2020 14:38'	System	22 Aug 2020 23:51:44

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '20 Aug 2020'	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14:35'	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '20 Aug 2020 14:35'	System	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered empty.	System	22 Aug 2020 23:52:03

US3092176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	22 Aug 2020 23:52:17

US3092176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	22 Aug 2020 23:52:17

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:19:50', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0bf08466-bbbb-4974-8b5b-4fff88c4f927'	System	20 Aug 2020 21:20:08
User entered 'Yes (Y)'	System	20 Aug 2020 21:20:08

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:19:55', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0bf08466-bbbb-4974-8b5b-4fff88c4f927'	System	20 Aug 2020 21:20:08
User entered '98.3'	System	20 Aug 2020 21:20:08

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0bf08466-bbbb-4974-8b5b-4fff88c4f927'	System	20 Aug 2020 21:20:08
User entered 'No (N)'	System	20 Aug 2020 21:20:08

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0bf08466-bbbb-4974-8b5b-4fff88c4f927'	System	20 Aug 2020 21:20:08
User entered '20 Aug 2020 16:20'	System	20 Aug 2020 21:20:08

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:27', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8386407b-fdfd-4a98-b60d-70232d56ccbc'	System	21 Aug 2020 13:40:42
User entered 'Yes (Y)'	System	21 Aug 2020 13:40:42

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8386407b-fdfd-4a98-b60d-70232d56ccbc'	System	21 Aug 2020 13:40:42
User entered '98.3'	System	21 Aug 2020 13:40:42

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:36', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8386407b-fdfd-4a98-b60d-70232d56ccbc'	System	21 Aug 2020 13:40:42
User entered 'No (N)'	System	21 Aug 2020 13:40:42

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8386407b-fdfd-4a98-b60d-70232d56ccbc'	System	21 Aug 2020 13:40:42
User entered '21 Aug 2020 08:40'	System	21 Aug 2020 13:40:42

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 19:19'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 2'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:31:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dcaa7b1f-34ae-4bfe-8014-adbbc23f0bc4'	System	22 Aug 2020 16:32:11
User entered 'Yes (Y)'	System	22 Aug 2020 16:32:11

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:32:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dcaa7b1f-34ae-4bfe-8014-adbbc23f0bc4'	System	22 Aug 2020 16:32:11
User entered '97.8'	System	22 Aug 2020 16:32:11

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:32:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dcaa7b1f-34ae-4bfe-8014-adbbc23f0bc4'	System	22 Aug 2020 16:32:11
User entered 'No (N)'	System	22 Aug 2020 16:32:11

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:32:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dcaa7b1f-34ae-4bfe-8014-adbbc23f0bc4'	System	22 Aug 2020 16:32:11
User entered '22 Aug 2020 11:32'	System	22 Aug 2020 16:32:11

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 3'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:42', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '64ad572e-52ab-403a-bd23-3fb08634a09f'	System	23 Aug 2020 12:19:56
User entered 'Yes (Y)'	System	23 Aug 2020 12:19:56

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:46', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '64ad572e-52ab-403a-bd23-3fb08634a09f'	System	23 Aug 2020 12:19:56
User entered '97.8'	System	23 Aug 2020 12:19:56

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:50', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '64ad572e-52ab-403a-bd23-3fb08634a09f'	System	23 Aug 2020 12:19:56
User entered 'No (N)'	System	23 Aug 2020 12:19:56

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:53', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '64ad572e-52ab-403a-bd23-3fb08634a09f'	System	23 Aug 2020 12:19:56
User entered '23 Aug 2020 07:19'	System	23 Aug 2020 12:19:56

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 4'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 5'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:17:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b111fb9-981b-4613-aab9-ba2c58110b59'	System	25 Aug 2020 02:18:28
User entered 'Yes (Y)'	System	25 Aug 2020 02:18:28

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:03', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b111fb9-981b-4613-aab9-ba2c58110b59'	System	25 Aug 2020 02:18:28
User entered '98.3'	System	25 Aug 2020 02:18:28

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b111fb9-981b-4613-aab9-ba2c58110b59'	System	25 Aug 2020 02:18:28
User entered 'Yes (Y)'	System	25 Aug 2020 02:18:28

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Advil 200mg x 4 tablets' (Site from System).		30 Oct 2020 12:25:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b111fb9-981b-4613-aab9-ba2c58110b59'	Catina Adams (b) (4) (b) (4)	23 Oct 2020 15:46:04
User entered '1'	System	25 Aug 2020 02:18:28
	System	25 Aug 2020 02:18:28
	System	25 Aug 2020 02:18:28

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b111fb9-981b-4613-aab9-ba2c58110b59'	System	25 Aug 2020 02:18:28
User entered '0'	System	25 Aug 2020 02:18:28

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b111fb9-981b-4613-aab9-ba2c58110b59'	System	25 Aug 2020 02:18:28
User entered '24 Aug 2020 21:18'	System	25 Aug 2020 02:18:28

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 6'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4467984a-f7a7-4203-a53a-4d9861169482'	System	25 Aug 2020 17:52:33
User entered 'Yes (Y)'	System	25 Aug 2020 17:52:33

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4467984a-f7a7-4203-a53a-4d9861169482'	System	25 Aug 2020 17:52:33
User entered '98.1'	System	25 Aug 2020 17:52:33

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:26', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4467984a-f7a7-4203-a53a-4d9861169482'	System	25 Aug 2020 17:52:33
User entered 'No (N)'	System	25 Aug 2020 17:52:33

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:29', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4467984a-f7a7-4203-a53a-4d9861169482'	System	25 Aug 2020 17:52:33
User entered '25 Aug 2020 12:52'	System	25 Aug 2020 17:52:33

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 7'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:27', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6cfd93f-6dbe-4c24-8fe5-e098814ddf1b'	System	26 Aug 2020 21:19:39
User entered 'Yes (Y)'	System	26 Aug 2020 21:19:39

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6cfd93f-6dbe-4c24-8fe5-e098814ddf1b'	System	26 Aug 2020 21:19:39
User entered '98.0'	System	26 Aug 2020 21:19:39

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:34', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6cfd93f-6dbe-4c24-8fe5-e098814ddf1b'	System	26 Aug 2020 21:19:39
User entered 'No (N)'	System	26 Aug 2020 21:19:39

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6cfd93f-6dbe-4c24-8fe5-e098814ddf1b'	System	26 Aug 2020 21:19:39
User entered '26 Aug 2020 16:19'	System	26 Aug 2020 21:19:39

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:13', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a3c49559-13e8-42c0-b814-e813dc7670ca'	System	20 Aug 2020 21:20:48
User entered 'None (1)'	System	20 Aug 2020 21:20:48

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:27', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a3c49559-13e8-42c0-b814-e813dc7670ca'	System	20 Aug 2020 21:20:48
User entered 'No (N)'	System	20 Aug 2020 21:20:48

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a3c49559-13e8-42c0-b814-e813dc7670ca'	System	20 Aug 2020 21:20:48
User entered 'No (N)'	System	20 Aug 2020 21:20:48

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:43', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a3c49559-13e8-42c0-b814-e813dc7670ca'	System	20 Aug 2020 21:20:48
User entered 'None (1)'	System	20 Aug 2020 21:20:48

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a3c49559-13e8-42c0-b814-e813dc7670ca'	System	20 Aug 2020 21:20:48
User entered '20 Aug 2020 16:20'	System	20 Aug 2020 21:20:48

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '25a1e94b-85fe-4075-800b-57415aeb81e2'	System	21 Aug 2020 13:39:46
User entered 'None (1)'	System	21 Aug 2020 13:39:46

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '25a1e94b-85fe-4075-800b-57415aeb81e2'	System	21 Aug 2020 13:39:46
User entered 'No (N)'	System	21 Aug 2020 13:39:46

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:29', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '25a1e94b-85fe-4075-800b-57415aeb81e2'	System	21 Aug 2020 13:39:46
User entered 'No (N)'	System	21 Aug 2020 13:39:46

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:38', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '25a1e94b-85fe-4075-800b-57415aeb81e2'	System	21 Aug 2020 13:39:46
User entered 'None (1)'	System	21 Aug 2020 13:39:46

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:42', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '25a1e94b-85fe-4075-800b-57415aeb81e2'	System	21 Aug 2020 13:39:46
User entered '21 Aug 2020 08:39'	System	21 Aug 2020 13:39:46

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 19:19'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 2'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:32:14', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:32:17', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered 'Yes (Y)'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:33:47', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered '4'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:33:51', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered 'Yes (Y)'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:34:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered '10'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:34:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '66206ec7-7b1b-4dd4-9b3e-3e858465c626'	System	22 Aug 2020 16:35:04
User entered '22 Aug 2020 11:35'	System	22 Aug 2020 16:35:04

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 3'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:18:31', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c6674800-9cc6-448a-b094-6aa07291bfcb'	System	23 Aug 2020 12:19:10
User entered 'None (1)'	System	23 Aug 2020 12:19:10

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:18:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c6674800-9cc6-448a-b094-6aa07291bfcb'	System	23 Aug 2020 12:19:10
User entered 'Yes (Y)'	System	23 Aug 2020 12:19:10

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:18:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c6674800-9cc6-448a-b094-6aa07291bfcb' User entered '4'	System	23 Aug 2020 12:19:10
	System	23 Aug 2020 12:19:10

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:18:49', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c6674800-9cc6-448a-b094-6aa07291bfcb'	System	23 Aug 2020 12:19:10
User entered 'No (N)'	System	23 Aug 2020 12:19:10

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c6674800-9cc6-448a-b094-6aa07291bfcb'	System	23 Aug 2020 12:19:10
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 12:19:10

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c6674800-9cc6-448a-b094-6aa07291bfcb'	System	23 Aug 2020 12:19:10
User entered '23 Aug 2020 07:19'	System	23 Aug 2020 12:19:10

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 4'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 5'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:29', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f'	System	25 Aug 2020 02:18:58
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f'	System	25 Aug 2020 02:18:58
User entered 'Yes (Y)'	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f'	System	25 Aug 2020 02:18:58
User entered '4'	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:41', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f'	System	25 Aug 2020 02:18:58
User entered 'Yes (Y)'	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:46', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f' User entered '4'	System	25 Aug 2020 02:18:58
	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:51', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f'	System	25 Aug 2020 02:18:58
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:53', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'df5eded2-969d-4e7e-8ca8-9b6628a9cd3f'	System	25 Aug 2020 02:18:58
User entered '24 Aug 2020 21:18'	System	25 Aug 2020 02:18:58

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 6'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '62186d3b-7e61-4c0f-8989-fc6a9b677a7b'	System	25 Aug 2020 17:52:59
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 17:52:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:41', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '62186d3b-7e61-4c0f-8989-fc6a9b677a7b'	System	25 Aug 2020 17:52:59
User entered 'No (N)'	System	25 Aug 2020 17:52:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '62186d3b-7e61-4c0f-8989-fc6a9b677a7b'	System	25 Aug 2020 17:52:59
User entered 'No (N)'	System	25 Aug 2020 17:52:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:48', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '62186d3b-7e61-4c0f-8989-fc6a9b677a7b'	System	25 Aug 2020 17:52:59
User entered 'None (1)'	System	25 Aug 2020 17:52:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:50', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '62186d3b-7e61-4c0f-8989-fc6a9b677a7b'	System	25 Aug 2020 17:52:59
User entered '25 Aug 2020 12:52'	System	25 Aug 2020 17:52:59

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 7'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:40', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b9c5fea-40e6-45b7-90be-37104d8c9eac'	System	26 Aug 2020 21:19:51
User entered 'None (1)'	System	26 Aug 2020 21:19:51

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:43', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b9c5fea-40e6-45b7-90be-37104d8c9eac'	System	26 Aug 2020 21:19:51
User entered 'No (N)'	System	26 Aug 2020 21:19:51

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b9c5fea-40e6-45b7-90be-37104d8c9eac'	System	26 Aug 2020 21:19:51
User entered 'No (N)'	System	26 Aug 2020 21:19:51

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:46', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b9c5fea-40e6-45b7-90be-37104d8c9eac'	System	26 Aug 2020 21:19:51
User entered 'None (1)'	System	26 Aug 2020 21:19:51

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:49', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0b9c5fea-40e6-45b7-90be-37104d8c9eac'	System	26 Aug 2020 21:19:51
User entered '26 Aug 2020 16:19'	System	26 Aug 2020 21:19:51

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:51', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'None (0)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:54', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'None (0)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'None (0)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:20:59', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'None (0)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:21:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'None (0)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:21:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'None (0)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:21:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered 'No (N)'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-20T16:21:15', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c780dd67-c195-41a1-a689-2160c9b8308e'	System	20 Aug 2020 21:21:20
User entered '20 Aug 2020 16:21'	System	20 Aug 2020 21:21:20

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:46', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'None (0)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:51', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'None (0)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:54', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'None (0)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:39:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'None (0)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'None (0)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:03', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'None (0)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered 'No (N)'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-21T08:40:15', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0208debf-30a5-4502-825d-e2986fc48e47'	System	21 Aug 2020 13:40:18
User entered '21 Aug 2020 08:40'	System	21 Aug 2020 13:40:18

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Aug 2020 19:19'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 2'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'None (0)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:20', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'None (0)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'None (0)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:26', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'None (0)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'None (0)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:31', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'None (0)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered 'No (N)'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-22T11:35:38', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '432ed4ad-9d01-48c6-a4e4-391cd58688c3'	System	22 Aug 2020 16:35:41
User entered '22 Aug 2020 11:35'	System	22 Aug 2020 16:35:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 3'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'None (0)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:16', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'None (0)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:20', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'None (0)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:29', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'None (0)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:31', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'None (0)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'None (0)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:35', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered 'No (N)'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-23T07:19:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '7145e980-e5cc-45dc-aa6b-63793c54661b'	System	23 Aug 2020 12:19:41
User entered '23 Aug 2020 07:19'	System	23 Aug 2020 12:19:41

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 4'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 5'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:18:59', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'No interference with activity (1)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'Some interference with activity (2)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'No interference with activity (1)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:14', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'Some interference with activity (2)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:17', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'None (0)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:20', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'None (0)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:25', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered 'No (N)'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-24T21:19:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '76187787-2751-43a3-9d9d-a4b55f3bb72d'	System	25 Aug 2020 02:19:33
User entered '24 Aug 2020 21:19'	System	25 Aug 2020 02:19:33

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 6'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:52:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'None (0)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'None (0)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'None (0)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'None (0)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:11', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'None (0)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:13', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'None (0)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:17', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered 'No (N)'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-25T12:53:20', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '89e0ff9d-5553-47f2-894f-7511e2b26184'	System	25 Aug 2020 17:53:25
User entered '25 Aug 2020 12:53'	System	25 Aug 2020 17:53:25

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 7'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:52', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered 'None (0)'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:53', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered 'None (0)'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:54', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered 'None (0)'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d' User entered 'None (0)'	System	26 Aug 2020 21:20:05
	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered 'None (0)'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:19:59', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered 'None (0)'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:20:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered 'No (N)'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-08-26T16:20:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0c318d10-4e9f-47c1-9fff-3672e818d02d'	System	26 Aug 2020 21:20:05
User entered '26 Aug 2020 16:20'	System	26 Aug 2020 21:20:05

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:58:34

US3092176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Aug 2020 17:15:21

US3092176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	(b) (4)	23 Oct 2020 15:25:43
User entered '28 Aug 2020' reason for change: Data Entry Error	System	23 Oct 2020 15:25:43
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Catina Adams (b) (4)	23 Oct 2020 15:25:43
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'protocol deviation ' (Site from System).	(b) (4)	17 Sep 2020 06:46:37
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 19:59:31
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	destiny robinson (b) (4)	(b) (4)
User entered '16 Aug 2020' reason for change: Data Entry Error	System	16 Sep 2020 19:24:04
User entered '28 Aug 2020'	System	16 Sep 2020 19:24:04
	System	16 Sep 2020 19:24:04
	destiny robinson (b) (4)	16 Sep 2020 19:24:04
	(b) (4)	16 Sep 2020 19:24:04
	Catina Adams (b) (4)	29 Aug 2020 17:15:21
	(b) (4)	

US3092176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	29 Aug 2020 17:15:21

US3092176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	29 Aug 2020 17:15:21

US3092176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	29 Aug 2020 17:15:29

US3092176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	29 Aug 2020 17:15:29

US3092176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
Signature has been broken.	Catina Adams (b) (4)	27 Mar 2021 10:32:24
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4)	27 Mar 2021 10:32:24
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	destiny robinson (b) (4)	16 Sep 2020 19:24:29

US3092176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User closed query 'Visits Safety Call Day 15 and Safety Call Day 22 are both dated 16SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM). User signature succeeded.	(b) (4)	29 Mar 2021 11:35:04
	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
Query 'Visits Safety Call Day 15 and Safety Call Day 22 are both dated 16SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' answered with 'Updated to call not attempted.' (Site from DM). Signature has been broken.	Catina Adams (b) (4)	27 Mar 2021 10:33:01
	Catina Adams (b) (4)	27 Mar 2021 10:32:24
User entered empty; reason for change Data Entry Error	Catina Adams (b) (4)	27 Mar 2021 10:32:24
User opened query 'Visits Safety Call Day 15 and Safety Call Day 22 are both dated 16SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Mar 2021 08:39:07
	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'protocol deviation ' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 06:46:58
	destiny robinson (b) (4)	16 Sep 2020 19:24:34

US3092176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 19:24:29
User entered '16 Sep 2020'	destiny robinson (b) (4) (b) (4)	16 Sep 2020 19:24:29

US3092176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
Signature has been broken.	Catina Adams (b) (4)	27 Mar 2021 10:32:24
User entered empty; reason for change Data Entry Error	Catina Adams (b) (4)	27 Mar 2021 10:32:24
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	destiny robinson (b) (4)	16 Sep 2020 19:24:29

US3092176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User closed query 'Per CDM: Was Contact Attempted? Is recorded as "No". However please provide the reason for contact not made in the Comments section. Else clarify.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 02:21:29
' (Site from DM). Query 'Per CDM: Was Contact Attempted? Is recorded as "No". However please provide the reason for contact not made in the Comments section. Else clarify.	(b) (4), (b) (6)	29 Mar 2021 14:26:14
' answered with 'DATA IS CORRECT, CALL WAS NOT ATTEMPTED, CALL WAS MISSED' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 14:26:01
User entered 'CALL WAS NOT ATTEMPTED, CALL WAS MISSED' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 14:26:01
User opened query 'Per CDM: Was Contact Attempted? Is recorded as "No". However please provide the reason for contact not made in the Comments section. Else clarify.		29 Mar 2021 11:35:24
' (Site from DM). User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Sep 2020 19:24:29

US3092176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	16 Sep 2020 19:24:38

US3092176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	16 Sep 2020 19:24:38

US3092176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Sep 2020 19:24:53

US3092176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 06:47:06
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'protocol deviation ' (Site from System).	destiny robinson (b) (4) (b) (4)	16 Sep 2020 19:29:30
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 19:24:53
User entered '16 Sep 2020'	destiny robinson (b) (4) (b) (4)	16 Sep 2020 19:24:53

US3092176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Sep 2020 19:24:53

US3092176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	destiny robinson (b) (4)	16 Sep 2020 19:24:53

US3092176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	destiny robinson (b) (4)	16 Sep 2020 19:29:33

US3092176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	16 Sep 2020 19:29:33

US3092176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:14:32

US3092176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020'	Catina Adams (b) (4)	18 Sep 2020 16:14:32

US3092176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	18 Sep 2020 16:14:32

US3092176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'VISIT2'	System	18 Sep 2020 16:14:32

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Pre-Dose (PREDOSE)'	Catina Adams (b) (4) (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '10:39'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '18 Sep 2020 10:39'	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '98.0' F	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '83'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'bpm'	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'breaths/min'	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '149'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '88'	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Post-Dose (POSTDOSE)'	Catina Adams (b) (4) (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 16:57:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 16:57:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 16:14:19
User entered empty.	System	18 Sep 2020 16:14:19
	Catina Adams (b) (4)	18 Sep 2020 16:14:19
	(b) (4)	

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19
	(b) (4)	

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:37' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '18 Sep 2020 11:37'	System	18 Sep 2020 16:57:36
User entered empty.	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '98.9' F reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '72' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'bpm'	System	18 Sep 2020 16:57:36
User entered empty.	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'breaths/min'	System	18 Sep 2020 16:57:36
User entered empty.	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '151' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	18 Sep 2020 16:57:36
User entered empty.	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '84' reason for change: Data Entry Error	Catina Adams (b) (4)	18 Sep 2020 16:57:36
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	18 Sep 2020 16:57:36
User entered empty.	System	18 Sep 2020 16:14:19

US3092176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:14:45

US3092176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020'	Catina Adams (b) (4)	18 Sep 2020 16:14:45

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020'	Catina Adams (b) (4)	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:05'	Catina Adams (b) (4)	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '18 Sep 2020 11:05'	System	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Left Arm (LEFT ARM)'	Catina Adams (b) (4)	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'ONCE'	System	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:15:14

US3092176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:15:34

US3092176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020'	Catina Adams (b) (4)	18 Sep 2020 16:15:34

US3092176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:02'	Catina Adams (b) (4)	18 Sep 2020 16:15:34

US3092176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '18 Sep 2020 11:02'	System	18 Sep 2020 16:15:34

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '18 Sep 2020'	Catina Adams (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Catina Adams (b) (4) (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '10:58'	Catina Adams (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '18 Sep 2020 10:58'	System	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Catina Adams (b) (4) (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:40:22
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:40:22
User entered '10:58'	Catina Adams (b) (4) (b) (4)	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered empty.	System	31 Dec 2020 18:40:22
User entered '18 Sep 2020 10:58'	System	18 Sep 2020 16:16:01

US3092176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	18 Sep 2020 16:16:15

US3092176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '1'	System	18 Sep 2020 16:16:15

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'adcae667-e1dc-4ac0-810e-8cf265b26bbf'	System	18 Sep 2020 16:35:17
User entered 'Yes (Y)'	System	18 Sep 2020 16:35:17

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'adcae667-e1dc-4ac0-810e-8cf265b26bbf'	System	18 Sep 2020 16:35:17
User entered '98.9'	System	18 Sep 2020 16:35:17

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'adcae667-e1dc-4ac0-810e-8cf265b26bbf'	System	18 Sep 2020 16:35:17
User entered 'No (N)'	System	18 Sep 2020 16:35:17

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:13', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'adcae667-e1dc-4ac0-810e-8cf265b26bbf'	System	18 Sep 2020 16:35:17
User entered '18 Sep 2020 11:35'	System	18 Sep 2020 16:35:17

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 11:25'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 13:55'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:27', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '38a55ca9-4319-4c50-8a99-89726e66989f'	System	18 Sep 2020 21:42:41
User entered 'Yes (Y)'	System	18 Sep 2020 21:42:41

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '38a55ca9-4319-4c50-8a99-89726e66989f' User entered '98.6'	System	18 Sep 2020 21:42:41
	System	18 Sep 2020 21:42:41

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:36', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '38a55ca9-4319-4c50-8a99-89726e66989f'	System	18 Sep 2020 21:42:41
User entered 'No (N)'	System	18 Sep 2020 21:42:41

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '38a55ca9-4319-4c50-8a99-89726e66989f'	System	18 Sep 2020 21:42:41
User entered '18 Sep 2020 16:42'	System	18 Sep 2020 21:42:41

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 14:50'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 2'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:22', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1f9d8f9-f7ee-44ac-b128-439e07d41ad7'	System	20 Sep 2020 01:48:37
User entered 'Yes (Y)'	System	20 Sep 2020 01:48:37

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1f9d8f9-f7ee-44ac-b128-439e07d41ad7'	System	20 Sep 2020 01:48:37
User entered '98.3'	System	20 Sep 2020 01:48:37

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:31', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1f9d8f9-f7ee-44ac-b128-439e07d41ad7'	System	20 Sep 2020 01:48:37
User entered 'No (N)'	System	20 Sep 2020 01:48:37

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:35', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1f9d8f9-f7ee-44ac-b128-439e07d41ad7'	System	20 Sep 2020 01:48:37
User entered '19 Sep 2020 20:48'	System	20 Sep 2020 01:48:37

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 3'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:48:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd7cf6307-8e6a-47d2-b173-664597834900'	System	20 Sep 2020 20:48:40
User entered 'Yes (Y)'	System	20 Sep 2020 20:48:40

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:48:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd7cf6307-8e6a-47d2-b173-664597834900'	System	20 Sep 2020 20:48:40
User entered '98.7'	System	20 Sep 2020 20:48:40

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:48:25', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd7cf6307-8e6a-47d2-b173-664597834900'	System	20 Sep 2020 20:48:40
User entered 'Yes (Y)'	System	20 Sep 2020 20:48:40

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took 800 mg advil' (Site from System).		30 Oct 2020 12:29:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Catina Adams (b) (4)	23 Oct 2020 15:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:48:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd7cf6307-8e6a-47d2-b173-664597834900'	(b) (4)	
User entered '1'	System	20 Sep 2020 20:48:40
	System	20 Sep 2020 20:48:40
	System	20 Sep 2020 20:48:40

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:48:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd7cf6307-8e6a-47d2-b173-664597834900' User entered '0'	System	20 Sep 2020 20:48:40
	System	20 Sep 2020 20:48:40

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:48:36', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd7cf6307-8e6a-47d2-b173-664597834900'	System	20 Sep 2020 20:48:40
User entered '20 Sep 2020 15:48'	System	20 Sep 2020 20:48:40

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 4'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '43dcfd53-e692-478a-9315-6f2145bc5353'	System	21 Sep 2020 23:03:45
User entered 'Yes (Y)'	System	21 Sep 2020 23:03:45

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '43dcfd53-e692-478a-9315-6f2145bc5353'	System	21 Sep 2020 23:03:45
User entered '97.6'	System	21 Sep 2020 23:03:45

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:34', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '43dcfd53-e692-478a-9315-6f2145bc5353'	System	21 Sep 2020 23:03:45
User entered 'Yes (Y)'	System	21 Sep 2020 23:03:45

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took 800mg advil' (Site from System).		30 Oct 2020 12:29:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Catina Adams (b) (4)	23 Oct 2020 15:55:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:38', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '43dcfd53-e692-478a-9315-6f2145bc5353'	(b) (4)	
User entered '1'	System	21 Sep 2020 23:03:45
	System	21 Sep 2020 23:03:45
	System	21 Sep 2020 23:03:45

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:38', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '43dcfd53-e692-478a-9315-6f2145bc5353' User entered '0'	System	21 Sep 2020 23:03:45
	System	21 Sep 2020 23:03:45

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:41', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '43dcfd53-e692-478a-9315-6f2145bc5353'	System	21 Sep 2020 23:03:45
User entered '21 Sep 2020 18:03'	System	21 Sep 2020 23:03:45

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 5'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-22T23:59:50', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b8050fd3-7200-45ef-b183-405aee3ff0d9'	System	23 Sep 2020 05:00:18
User entered 'Yes (Y)'	System	23 Sep 2020 05:00:18

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-22T23:59:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b8050fd3-7200-45ef-b183-405aee3ff0d9'	System	23 Sep 2020 05:00:18
User entered '97.3'	System	23 Sep 2020 05:00:18

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b8050fd3-7200-45ef-b183-405aee3ff0d9'	System	23 Sep 2020 05:00:18
User entered 'Yes (Y)'	System	23 Sep 2020 05:00:18

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took 800mg advil' (Site from System).		30 Oct 2020 12:29:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Catina Adams (b) (4)	23 Oct 2020 15:55:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b8050fd3-7200-45ef-b183-405aee3ff0d9'	(b) (4)	
User entered '1'	System	23 Sep 2020 05:00:18
	System	23 Sep 2020 05:00:18
	System	23 Sep 2020 05:00:18

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b8050fd3-7200-45ef-b183-405aee3ff0d9'	System	23 Sep 2020 05:00:18
User entered '0'	System	23 Sep 2020 05:00:18

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b8050fd3-7200-45ef-b183-405aee3ff0d9'	System	23 Sep 2020 05:00:18
User entered '23 Sep 2020 00:00'	System	23 Sep 2020 05:00:18

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 6'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:03:47', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '325f7826-841d-4f5d-9cf2-df6d6083ec13'	System	23 Sep 2020 18:04:10
User entered 'Yes (Y)'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:03:52', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '325f7826-841d-4f5d-9cf2-df6d6083ec13'	System	23 Sep 2020 18:04:10
User entered '97.7'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:03:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '325f7826-841d-4f5d-9cf2-df6d6083ec13'	System	23 Sep 2020 18:04:10
User entered 'Yes (Y)'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took 800mg advil' (Site from System).		30 Oct 2020 12:29:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Catina Adams (b) (4)	23 Oct 2020 15:56:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '325f7826-841d-4f5d-9cf2-df6d6083ec13'	(b) (4)	
User entered '1'	System	23 Sep 2020 18:04:10
	System	23 Sep 2020 18:04:10
	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '325f7826-841d-4f5d-9cf2-df6d6083ec13'	System	23 Sep 2020 18:04:10
User entered '0'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:03', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '325f7826-841d-4f5d-9cf2-df6d6083ec13'	System	23 Sep 2020 18:04:10
User entered '23 Sep 2020 13:04'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 7'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:43:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b1e3e2c-7b3b-4865-8273-331e4b32f811'	System	25 Sep 2020 06:44:19
User entered 'Yes (Y)'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b1e3e2c-7b3b-4865-8273-331e4b32f811'	System	25 Sep 2020 06:44:19
User entered '97.8'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b1e3e2c-7b3b-4865-8273-331e4b32f811'	System	25 Sep 2020 06:44:19
User entered 'Yes (Y)'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took 800mg advil' (Site from System).		30 Oct 2020 12:29:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Catina Adams (b) (4)	23 Oct 2020 15:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:13', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b1e3e2c-7b3b-4865-8273-331e4b32f811'	(b) (4)	
User entered '1'	System	25 Sep 2020 06:44:19
	System	25 Sep 2020 06:44:19
	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:13', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b1e3e2c-7b3b-4865-8273-331e4b32f811'	System	25 Sep 2020 06:44:19
User entered '0'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:16', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b1e3e2c-7b3b-4865-8273-331e4b32f811'	System	25 Sep 2020 06:44:19
User entered '25 Sep 2020 01:44'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	23 Sep 2020 18:04:10
User entered 'Day 8'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:00:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd0cf54cd-c613-4645-b4f1-962e761a92b3'	System	25 Sep 2020 17:02:03
User entered 'Yes (Y)'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:00:52', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd0cf54cd-c613-4645-b4f1-962e761a92b3'	System	25 Sep 2020 17:02:03
User entered '98.3'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:00:55', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd0cf54cd-c613-4645-b4f1-962e761a92b3'	System	25 Sep 2020 17:02:03
User entered 'Yes (Y)'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took 800 mg advil' (Site from System).		30 Oct 2020 12:29:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Catina Adams (b) (4)	23 Oct 2020 15:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:00:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd0cf54cd-c613-4645-b4f1-962e761a92b3'	(b) (4)	
User entered '1'	System	25 Sep 2020 17:02:03
	System	25 Sep 2020 17:02:03
	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:00:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd0cf54cd-c613-4645-b4f1-962e761a92b3'	System	25 Sep 2020 17:02:03
User entered '0'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:01:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd0cf54cd-c613-4645-b4f1-962e761a92b3'	System	25 Sep 2020 17:02:03
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	25 Sep 2020 06:44:19
User entered 'Day 9'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	25 Sep 2020 17:02:03
User entered 'Day 10'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:24', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9d6ee92e-a9db-4b8e-913f-6b3fee4ec349'	System	18 Sep 2020 16:35:45
User entered 'None (1)'	System	18 Sep 2020 16:35:45

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:30', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9d6ee92e-a9db-4b8e-913f-6b3fee4ec349'	System	18 Sep 2020 16:35:45
User entered 'No (N)'	System	18 Sep 2020 16:35:45

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:33', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9d6ee92e-a9db-4b8e-913f-6b3fee4ec349'	System	18 Sep 2020 16:35:45
User entered 'No (N)'	System	18 Sep 2020 16:35:45

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9d6ee92e-a9db-4b8e-913f-6b3fee4ec349'	System	18 Sep 2020 16:35:45
User entered 'None (1)'	System	18 Sep 2020 16:35:45

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9d6ee92e-a9db-4b8e-913f-6b3fee4ec349'	System	18 Sep 2020 16:35:45
User entered '18 Sep 2020 11:35'	System	18 Sep 2020 16:35:45

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 11:25'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 13:55'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:46', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a'	System	18 Sep 2020 21:43:12
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:49', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a'	System	18 Sep 2020 21:43:12
User entered 'Yes (Y)'	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a' User entered '7'	System	18 Sep 2020 21:43:12
	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:42:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a'	System	18 Sep 2020 21:43:12
User entered 'Yes (Y)'	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:04', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a'	System	18 Sep 2020 21:43:12
User entered '4'	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a'	System	18 Sep 2020 21:43:12
User entered 'None (1)'	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:10', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd949a4ee-626e-46c1-a298-434a8494c51a'	System	18 Sep 2020 21:43:12
User entered '18 Sep 2020 16:43'	System	18 Sep 2020 21:43:12

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 14:50'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 2'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bcecdceb-d413-463a-820a-b1ca3aa97983'	System	20 Sep 2020 01:49:06
User entered 'None (1)'	System	20 Sep 2020 01:49:06

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:42', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bcecdceb-d413-463a-820a-b1ca3aa97983'	System	20 Sep 2020 01:49:06
User entered 'No (N)'	System	20 Sep 2020 01:49:06

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bcecddeb-d413-463a-820a-b1ca3aa97983'	System	20 Sep 2020 01:49:06
User entered 'No (N)'	System	20 Sep 2020 01:49:06

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:48:55', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bcecddeb-d413-463a-820a-b1ca3aa97983'	System	20 Sep 2020 01:49:06
User entered 'None (1)'	System	20 Sep 2020 01:49:06

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bcecdceb-d413-463a-820a-b1ca3aa97983'	System	20 Sep 2020 01:49:06
User entered '19 Sep 2020 20:49'	System	20 Sep 2020 01:49:06

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 3'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'f562c71f-4cc1-4c2c-bfab-79c2bef7819a'	System	20 Sep 2020 20:50:41
User entered 'None (1)'	System	20 Sep 2020 20:50:41

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'f562c71f-4cc1-4c2c-bfab-79c2bef7819a'	System	20 Sep 2020 20:50:41
User entered 'No (N)'	System	20 Sep 2020 20:50:41

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:11', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'f562c71f-4cc1-4c2c-bfab-79c2bef7819a'	System	20 Sep 2020 20:50:41
User entered 'No (N)'	System	20 Sep 2020 20:50:41

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:35', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'f562c71f-4cc1-4c2c-bfab-79c2bef7819a'	System	20 Sep 2020 20:50:41
User entered 'None (1)'	System	20 Sep 2020 20:50:41

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'f562c71f-4cc1-4c2c-bfab-79c2bef7819a'	System	20 Sep 2020 20:50:41
User entered '20 Sep 2020 15:50'	System	20 Sep 2020 20:50:41

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 4'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd5146fcf-6e6a-41bc-8014-34227ec8a114'	System	21 Sep 2020 23:04:35
User entered 'None (1)'	System	21 Sep 2020 23:04:35

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:03:50', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd5146fcf-6e6a-41bc-8014-34227ec8a114'	System	21 Sep 2020 23:04:35
User entered 'No (N)'	System	21 Sep 2020 23:04:35

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:14', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd5146fcf-6e6a-41bc-8014-34227ec8a114'	System	21 Sep 2020 23:04:35
User entered 'No (N)'	System	21 Sep 2020 23:04:35

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd5146fcf-6e6a-41bc-8014-34227ec8a114'	System	21 Sep 2020 23:04:35
User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 23:04:35

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:30', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'd5146fcf-6e6a-41bc-8014-34227ec8a114'	System	21 Sep 2020 23:04:35
User entered '21 Sep 2020 18:04'	System	21 Sep 2020 23:04:35

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 5'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:16', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '1913e8c1-6f97-46f9-87fe-4c85412899db'	System	23 Sep 2020 05:00:37
User entered 'None (1)'	System	23 Sep 2020 05:00:37

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:20', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '1913e8c1-6f97-46f9-87fe-4c85412899db'	System	23 Sep 2020 05:00:37
User entered 'No (N)'	System	23 Sep 2020 05:00:37

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:24', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '1913e8c1-6f97-46f9-87fe-4c85412899db'	System	23 Sep 2020 05:00:37
User entered 'No (N)'	System	23 Sep 2020 05:00:37

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '1913e8c1-6f97-46f9-87fe-4c85412899db'	System	23 Sep 2020 05:00:37
User entered 'None (1)'	System	23 Sep 2020 05:00:37

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:31', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '1913e8c1-6f97-46f9-87fe-4c85412899db'	System	23 Sep 2020 05:00:37
User entered '23 Sep 2020 00:00'	System	23 Sep 2020 05:00:37

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 6'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0158f7ad-5e6a-4e08-972a-4dcee21bc94b'	System	23 Sep 2020 18:04:23
User entered 'None (1)'	System	23 Sep 2020 18:04:23

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:10', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0158f7ad-5e6a-4e08-972a-4dcee21bc94b'	System	23 Sep 2020 18:04:23
User entered 'No (N)'	System	23 Sep 2020 18:04:23

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0158f7ad-5e6a-4e08-972a-4dcee21bc94b'	System	23 Sep 2020 18:04:23
User entered 'No (N)'	System	23 Sep 2020 18:04:23

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:16', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0158f7ad-5e6a-4e08-972a-4dcee21bc94b'	System	23 Sep 2020 18:04:23
User entered 'None (1)'	System	23 Sep 2020 18:04:23

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0158f7ad-5e6a-4e08-972a-4dcee21bc94b'	System	23 Sep 2020 18:04:23
User entered '23 Sep 2020 13:04'	System	23 Sep 2020 18:04:23

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 7'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:22', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e5f67aa3-c4c0-48b1-8a1c-2296a8c1f546'	System	25 Sep 2020 06:44:39
User entered 'None (1)'	System	25 Sep 2020 06:44:39

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:25', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e5f67aa3-c4c0-48b1-8a1c-2296a8c1f546'	System	25 Sep 2020 06:44:39
User entered 'No (N)'	System	25 Sep 2020 06:44:39

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:28', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e5f67aa3-c4c0-48b1-8a1c-2296a8c1f546'	System	25 Sep 2020 06:44:39
User entered 'No (N)'	System	25 Sep 2020 06:44:39

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e5f67aa3-c4c0-48b1-8a1c-2296a8c1f546'	System	25 Sep 2020 06:44:39
User entered 'None (1)'	System	25 Sep 2020 06:44:39

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:35', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e5f67aa3-c4c0-48b1-8a1c-2296a8c1f546'	System	25 Sep 2020 06:44:39
User entered '25 Sep 2020 01:44'	System	25 Sep 2020 06:44:39

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:43', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'None (0)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'None (0)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:47', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'None (0)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:49', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'None (0)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:51', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'None (0)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:52', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'None (0)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:55', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered 'No (N)'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T11:35:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '48a02521-6ff6-44f8-85e6-179ab3765fa1'	System	18 Sep 2020 16:36:00
User entered '18 Sep 2020 11:35'	System	18 Sep 2020 16:36:00

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 11:25'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 13:55'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'None (0)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:21', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'None (0)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'None (0)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:27', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'None (0)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:29', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'None (0)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'None (0)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:36', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered 'No (N)'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-18T16:43:38', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a18f09f3-4f24-44e8-aef1-08f9dfecfba2'	System	18 Sep 2020 21:43:41
User entered '18 Sep 2020 16:43'	System	18 Sep 2020 21:43:41

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '18 Sep 2020 14:50'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 2'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:11', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'None (0)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:22', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'None (0)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:25', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'None (0)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'None (0)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:35', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'None (0)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:38', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'None (0)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:43', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered 'No (N)'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-19T20:49:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4c52ab2f-3091-4a44-8cad-10c2972e6940'	System	20 Sep 2020 01:49:48
User entered '19 Sep 2020 20:49'	System	20 Sep 2020 01:49:48

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 3'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:42', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'None (0)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'Some interference with activity (2)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:49', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'No interference with activity (1)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'None (0)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:50:58', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'None (0)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:51:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'None (0)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:51:03', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered 'No (N)'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-20T15:51:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a639c085-587d-4fe7-9343-5269ff849037'	System	20 Sep 2020 20:51:09
User entered '20 Sep 2020 15:51'	System	20 Sep 2020 20:51:09

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 4'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:35', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'No interference with activity (1)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:40', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'Some interference with activity (2)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:49', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'Some interference with activity (2)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:04:55', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'No interference with activity (1)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:05:04', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:05:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'None (0)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:05:16', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered 'No (N)'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-21T18:05:19', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b9b56749-9dae-47ea-a9ea-e07050dad596'	System	21 Sep 2020 23:05:22
User entered '21 Sep 2020 18:05'	System	21 Sep 2020 23:05:22

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 5'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'No interference with activity (1)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'No interference with activity (1)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:41', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'No interference with activity (1)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:43', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'No interference with activity (1)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:54', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'None (0)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:00:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'None (0)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:01:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered 'No (N)'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T00:01:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'dfdb8175-6758-4d8f-b163-35bc37f2e3dc'	System	23 Sep 2020 05:01:07
User entered '23 Sep 2020 00:01'	System	23 Sep 2020 05:01:07

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 6'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'None (0)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:27', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'None (0)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:39', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'None (0)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:42', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'None (0)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'None (0)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:48', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered 'No (N)'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-23T13:04:50', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bbb2604a-a693-4101-a3c9-d68b1544ea3e'	System	23 Sep 2020 18:04:53
User entered '23 Sep 2020 13:04'	System	23 Sep 2020 18:04:53

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	18 Sep 2020 16:15:14
User entered 'Day 7'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:42', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'None (0)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:45', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'None (0)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:48', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'None (0)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:52', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'None (0)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:54', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'None (0)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:44:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'None (0)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:45:01', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered 'No (N)'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T01:45:04', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '4b0d4ec3-0042-43b2-b81d-339e7be78f82'	System	25 Sep 2020 06:45:08
User entered '25 Sep 2020 01:45'	System	25 Sep 2020 06:45:08

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:15:14

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	23 Sep 2020 18:04:10
User entered 'Day 8'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:01:05', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8aed7baf-fa24-4b20-9143-a3a197c74db6'	System	25 Sep 2020 17:02:15
User entered 'No (N)'	System	25 Sep 2020 17:02:15

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-09-25T12:01:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8aed7baf-fa24-4b20-9143-a3a197c74db6'	System	25 Sep 2020 17:02:15
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:15

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:04:10

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	25 Sep 2020 06:44:19
User entered 'Day 9'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 06:44:19

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	25 Sep 2020 17:02:03
User entered 'Day 10'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:08:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:08:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:02:03

US3092176

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:08:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:02:03

US3092176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	28 Sep 2020 17:29:18

US3092176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '26 Sep 2020'	Catina Adams (b) (4)	28 Sep 2020 17:29:18

US3092176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	28 Sep 2020 17:29:18

US3092176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	28 Sep 2020 17:29:18

US3092176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	28 Sep 2020 17:29:26

US3092176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	28 Sep 2020 17:29:26

US3092176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Oct 2020 13:57:55

US3092176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '5 Oct 2020'	Catina Adams (b) (4)	05 Oct 2020 13:57:55

US3092176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4)	05 Oct 2020 13:57:55

US3092176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	05 Oct 2020 13:57:55

US3092176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Oct 2020 13:58:02

US3092176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	05 Oct 2020 13:58:02

US3092176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	10 Oct 2020 18:24:07

US3092176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '10 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	10 Oct 2020 18:24:07

US3092176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	10 Oct 2020 18:24:07

US3092176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	destiny robinson (b) (4)	10 Oct 2020 18:24:07

US3092176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	destiny robinson (b) (4)	10 Oct 2020 18:24:11

US3092176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	10 Oct 2020 18:24:11

US3092176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Oct 2020 16:28:34

US3092176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16 Oct 2020'	Catina Adams (b) (4)	16 Oct 2020 16:28:34

US3092176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	16 Oct 2020 16:28:34

US3092176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'VISIT3'	System	16 Oct 2020 16:28:34

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16 Oct 2020'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '10:55'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '16 Oct 2020 10:55'	System	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '98.5' F	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '91'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'bpm'	System	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'breaths/min'	System	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '131'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '82'	Catina Adams (b) (4)	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	16 Oct 2020 16:30:10

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42

US3092176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42

US3092176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Oct 2020 16:28:46

US3092176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16 Oct 2020'	Catina Adams (b) (4)	16 Oct 2020 16:28:46

US3092176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Oct 2020 16:29:06

US3092176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16 Oct 2020'	Catina Adams (b) (4)	16 Oct 2020 16:29:06

US3092176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:05'	Catina Adams (b) (4)	16 Oct 2020 16:29:06

US3092176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '16 Oct 2020 11:05'	System	16 Oct 2020 16:29:06

US3092176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Oct 2020 16:29:16

US3092176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '1'	System	16 Oct 2020 16:29:16

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 64'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Have you been exposed to someone with 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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Please 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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Please 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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 71'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-10-28T18:58:19', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b841592-6b07-4dba-9469-4eacb4f864cc'	System	28 Oct 2020 23:58:41
User entered 'No (N)'	System	28 Oct 2020 23:58:41

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-10-28T18:58:32', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b841592-6b07-4dba-9469-4eacb4f864cc'	System	28 Oct 2020 23:58:41
User entered 'No (N)'	System	28 Oct 2020 23:58:41

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-10-28T18:58:37', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2b841592-6b07-4dba-9469-4eacb4f864cc'	System	28 Oct 2020 23:58:41
User entered '28 Oct 2020 18:58:37'	System	28 Oct 2020 23:58:41

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 78'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:08:16

[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 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:08:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08

US3092176

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:07:08
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered 'Day 92'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-11-17T06:07:55', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0233d39f-f088-4c36-8cd2-8f8ba3ed0cfc'	System	17 Nov 2020 12:19:09
User entered 'No (N)'	System	17 Nov 2020 12:19:09

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-11-17T06:08:04', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0233d39f-f088-4c36-8cd2-8f8ba3ed0cfc'	System	17 Nov 2020 12:19:09
User entered 'No (N)'	System	17 Nov 2020 12:19:09

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-11-17T06:08:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0233d39f-f088-4c36-8cd2-8f8ba3ed0cfc' User entered '17 Nov 2020 06:08:09'	System	17 Nov 2020 12:19:09
	System	17 Nov 2020 12:19:09

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 20:58:34

US3092176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:20:14
Data entry locked.	System	20 Aug 2020 20:58:34
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 20:58:34

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2020-12-12T05:28:48', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '42533f65-1bdb-4309-a2ef-35489b0b0414'	System	12 Dec 2020 11:29:08
User entered 'No (N)'	System	12 Dec 2020 11:29:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2020-12-12T05:29:02', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '42533f65-1bdb-4309-a2ef-35489b0b0414'	System	12 Dec 2020 11:29:08
User entered 'No (N)'	System	12 Dec 2020 11:29:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-12-12T05:29:06', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '42533f65-1bdb-4309-a2ef-35489b0b0414'	System	12 Dec 2020 11:29:08
User entered '12 Dec 2020 05:29:06'	System	12 Dec 2020 11:29:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2020-12-23T10:07:18', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e6a67c8a-0c48-4179-9983-a0003a547136'	System	23 Dec 2020 16:34:19
User entered 'No (N)'	System	23 Dec 2020 16:34:19

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2020-12-23T10:34:11', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e6a67c8a-0c48-4179-9983-a0003a547136'	System	23 Dec 2020 16:34:19
User entered 'No (N)'	System	23 Dec 2020 16:34:19

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-12-23T10:34:14', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'e6a67c8a-0c48-4179-9983-a0003a547136'	System	23 Dec 2020 16:34:19
User entered '23 Dec 2020 10:34:14'	System	23 Dec 2020 16:34:19

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2020-12-26T05:13:29', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b65b9ad2-85c1-455b-b6ef-c96ab40830dd'	System	26 Dec 2020 11:14:02
User entered 'No (N)'	System	26 Dec 2020 11:14:02

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2020-12-26T05:13:54', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b65b9ad2-85c1-455b-b6ef-c96ab40830dd'	System	26 Dec 2020 11:14:02
User entered 'No (N)'	System	26 Dec 2020 11:14:02

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2020-12-26T05:13:57', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b65b9ad2-85c1-455b-b6ef-c96ab40830dd' User entered '26 Dec 2020 05:13:57'	System	26 Dec 2020 11:14:02
	System	26 Dec 2020 11:14:02

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-01-02T08:36:09', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6c9d497f-8bac-4a69-89cf-4fed8548d475'	System	02 Jan 2021 14:36:25
User entered 'No (N)'	System	02 Jan 2021 14:36:25

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-01-02T08:36:20', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6c9d497f-8bac-4a69-89cf-4fed8548d475'	System	02 Jan 2021 14:36:25
User entered 'No (N)'	System	02 Jan 2021 14:36:25

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-01-02T08:36:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '6c9d497f-8bac-4a69-89cf-4fed8548d475'	System	02 Jan 2021 14:36:25
User entered '02 Jan 2021 08:36:23'	System	02 Jan 2021 14:36:25

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-01-11T11:36:51', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0983c74d-2b40-4f2b-9edb-c6d4983dbf12'	System	11 Jan 2021 17:37:13
User entered 'No (N)'	System	11 Jan 2021 17:37:13

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-01-11T11:37:04', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0983c74d-2b40-4f2b-9edb-c6d4983dbf12'	System	11 Jan 2021 17:37:13
User entered 'No (N)'	System	11 Jan 2021 17:37:13

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-01-11T11:37:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0983c74d-2b40-4f2b-9edb-c6d4983dbf12'	System	11 Jan 2021 17:37:13
User entered '11 Jan 2021 11:37:08'	System	11 Jan 2021 17:37:13

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-01-16T02:53:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ccab9be-af2f-43dd-bf9f-188b6de94d72'	System	16 Jan 2021 08:54:08
User entered 'No (N)'	System	16 Jan 2021 08:54:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-01-16T02:54:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ccab9be-af2f-43dd-bf9f-188b6de94d72'	System	16 Jan 2021 08:54:08
User entered 'No (N)'	System	16 Jan 2021 08:54:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-01-16T02:54:04', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ccab9be-af2f-43dd-bf9f-188b6de94d72'	System	16 Jan 2021 08:54:08
User entered '16 Jan 2021 02:54:04'	System	16 Jan 2021 08:54:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-01-23T09:10:53', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a384e120-e484-4693-9f9d-54ece7e67c0d'	System	23 Jan 2021 15:11:10
User entered 'No (N)'	System	23 Jan 2021 15:11:10

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-01-23T09:11:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a384e120-e484-4693-9f9d-54ece7e67c0d'	System	23 Jan 2021 15:11:10
User entered 'No (N)'	System	23 Jan 2021 15:11:10

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-01-23T09:11:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a384e120-e484-4693-9f9d-54ece7e67c0d' User entered '23 Jan 2021 09:11:08'	System	23 Jan 2021 15:11:10

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-02-03T15:20:53', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9366d234-cf2c-44a9-bf15-594f96ffd410'	System	03 Feb 2021 21:21:08
User entered 'No (N)'	System	03 Feb 2021 21:21:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-02-03T15:21:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9366d234-cf2c-44a9-bf15-594f96ffd410'	System	03 Feb 2021 21:21:08
User entered 'No (N)'	System	03 Feb 2021 21:21:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-03T15:21:03', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9366d234-cf2c-44a9-bf15-594f96ffd410'	System	03 Feb 2021 21:21:08
User entered '03 Feb 2021 15:21:03'	System	03 Feb 2021 21:21:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-02-06T09:20:41', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8d3ce308-35f8-48ca-8209-34291f0eab48'	System	06 Feb 2021 15:21:10
User entered 'No (N)'	System	06 Feb 2021 15:21:10

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-02-06T09:20:46', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8d3ce308-35f8-48ca-8209-34291f0eab48'	System	06 Feb 2021 15:21:10
User entered 'No (N)'	System	06 Feb 2021 15:21:10

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-06T09:21:07', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '8d3ce308-35f8-48ca-8209-34291f0eab48'	System	06 Feb 2021 15:21:10
User entered '06 Feb 2021 09:21:07'	System	06 Feb 2021 15:21:10

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:15', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered 'Yes (Y)'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:23', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered 'No (N)'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:30', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered 'Yes (Y)'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '1'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '1'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '1'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '1'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:44', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '0'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:29:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:30:08', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered 'No (N)'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-13T05:30:12', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9da1e78c-27a2-48a9-889f-b5d1c269b1f3'	System	13 Feb 2021 11:30:21
User entered '13 Feb 2021 05:30:12'	System	13 Feb 2021 11:30:21

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-02-22T16:08:14', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b68d74e4-ef84-413a-bb9c-a21fdaee776d'	System	22 Feb 2021 22:09:08
User entered 'No (N)'	System	22 Feb 2021 22:09:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-02-22T16:08:56', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b68d74e4-ef84-413a-bb9c-a21fdae776d'	System	22 Feb 2021 22:09:08
User entered 'No (N)'	System	22 Feb 2021 22:09:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-22T16:09:03', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'b68d74e4-ef84-413a-bb9c-a21fdaee776d'	System	22 Feb 2021 22:09:08
User entered '22 Feb 2021 16:09:03'	System	22 Feb 2021 22:09:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-02-27T00:07:40-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'fbee91c3-71c2-4092-8eb1-cfebb5da948e' User entered 'No (N)'	System	27 Feb 2021 06:07:54

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-02-27T00:07:47-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'fbee91c3-71c2-4092-8eb1-cfebb5da948e'	System	27 Feb 2021 06:07:54
User entered 'No (N)'	System	27 Feb 2021 06:07:54

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-27T00:07:50-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'fbee91c3-71c2-4092-8eb1-cfebb5da948e' User entered '27 Feb 2021 00:07:50'	System	27 Feb 2021 06:07:54
	System	27 Feb 2021 06:07:54

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-03-08T18:56:04-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9218c860-56fa-4f16-a6a5-607b4edc37c3'	System	09 Mar 2021 00:56:17
User entered 'No (N)'	System	09 Mar 2021 00:56:17

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-03-08T18:56:11-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9218c860-56fa-4f16-a6a5-607b4edc37c3'	System	09 Mar 2021 00:56:17
User entered 'No (N)'	System	09 Mar 2021 00:56:17

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-03-08T18:56:13-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '9218c860-56fa-4f16-a6a5-607b4edc37c3'	System	09 Mar 2021 00:56:17
User entered '08 Mar 2021 18:56:13'	System	09 Mar 2021 00:56:17

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-03-16T22:26:00-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1eb63ee-be18-486d-8e52-e4f82dd7a72c'	System	17 Mar 2021 03:26:14
User entered 'No (N)'	System	17 Mar 2021 03:26:14

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-03-16T22:26:08-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1eb63ee-be18-486d-8e52-e4f82dd7a72c'	System	17 Mar 2021 03:26:14
User entered 'No (N)'	System	17 Mar 2021 03:26:14

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-03-16T22:26:11-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'a1eb63ee-be18-486d-8e52-e4f82dd7a72c'	System	17 Mar 2021 03:26:14
User entered '16 Mar 2021 22:26:11'	System	17 Mar 2021 03:26:14

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-03-21T11:22:35-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'ec349f05-7b11-46cd-892e-51a1ee4442d3'	System	21 Mar 2021 16:22:45
User entered 'No (N)'	System	21 Mar 2021 16:22:45

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-03-21T11:22:38-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'ec349f05-7b11-46cd-892e-51a1ee4442d3'	System	21 Mar 2021 16:22:45
User entered 'No (N)'	System	21 Mar 2021 16:22:45

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-03-21T11:22:40-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'ec349f05-7b11-46cd-892e-51a1ee4442d3'	System	21 Mar 2021 16:22:45
User entered '21 Mar 2021 11:22:40'	System	21 Mar 2021 16:22:45

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-03-29T18:59:16-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '836518a0-dffa-4bf0-819b-a03974a450a3'	System	29 Mar 2021 23:59:27
User entered 'No (N)'	System	29 Mar 2021 23:59:27

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-03-29T18:59:20-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '836518a0-dffa-4bf0-819b-a03974a450a3'	System	29 Mar 2021 23:59:27
User entered 'No (N)'	System	29 Mar 2021 23:59:27

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-03-29T18:59:23-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '836518a0-dffa-4bf0-819b-a03974a450a3'	System	29 Mar 2021 23:59:27
User entered '29 Mar 2021 18:59:23'	System	29 Mar 2021 23:59:27

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-04-03T09:40:12-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c13922ff-f847-4e5c-bdbc-d2d1f109a9ae'	System	03 Apr 2021 14:40:59
User entered 'Yes (Y)'	System	03 Apr 2021 14:40:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-04-03T09:40:19-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c13922ff-f847-4e5c-bdbc-d2d1f109a9ae'	System	03 Apr 2021 14:40:59
User entered 'No (N)'	System	03 Apr 2021 14:40:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-03T09:40:26-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c13922ff-f847-4e5c-bdbc-d2d1f109a9ae'	System	03 Apr 2021 14:40:59
User entered 'No (N)'	System	03 Apr 2021 14:40:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-03T09:40:40-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c13922ff-f847-4e5c-bdbc-d2d1f109a9ae'	System	03 Apr 2021 14:40:59
User entered 'No (N)'	System	03 Apr 2021 14:40:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-03T09:40:55-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'c13922ff-f847-4e5c-bdbc-d2d1f109a9ae'	System	03 Apr 2021 14:40:59
User entered '03 Apr 2021 09:40:55'	System	03 Apr 2021 14:40:59

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-04-13T14:15:58-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ab0b932-dffb-47b1-a3e1-c25211829ff8'	System	13 Apr 2021 19:16:39
User entered 'Yes (Y)'	System	13 Apr 2021 19:16:39

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-04-13T14:16:02-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ab0b932-dffb-47b1-a3e1-c25211829ff8'	System	13 Apr 2021 19:16:39
User entered 'No (N)'	System	13 Apr 2021 19:16:39

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-13T14:16:08-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ab0b932-dffb-47b1-a3e1-c25211829ff8'	System	13 Apr 2021 19:16:39
User entered 'No (N)'	System	13 Apr 2021 19:16:39

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-13T14:16:14-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ab0b932-dffb-47b1-a3e1-c25211829ff8'	System	13 Apr 2021 19:16:39
User entered 'Yes (Y)'	System	13 Apr 2021 19:16:39

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-13T14:16:19-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ab0b932-dffb-47b1-a3e1-c25211829ff8'	System	13 Apr 2021 19:16:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Apr 2021 19:16:39

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-13T14:16:24-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '2ab0b932-dffb-47b1-a3e1-c25211829ff8'	System	13 Apr 2021 19:16:39
User entered '13 Apr 2021 14:16:24'	System	13 Apr 2021 19:16:39

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-04-19T17:19:37-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '3296d973-5098-4eaf-b8d9-3f14059875ca' User entered 'No (N)'	System	19 Apr 2021 22:19:46
	System	19 Apr 2021 22:19:46

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-04-19T17:19:41-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '3296d973-5098-4eaf-b8d9-3f14059875ca' User entered 'No (N)'	System	19 Apr 2021 22:19:46

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-19T17:19:44-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '3296d973-5098-4eaf-b8d9-3f14059875ca' User entered '19 Apr 2021 17:19:44'	System	19 Apr 2021 22:19:46
	System	19 Apr 2021 22:19:46

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-04-24T07:25:53-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bfda95ca-9e7f-47e1-a38f-83090b7c1244'	System	24 Apr 2021 12:26:03
User entered 'No (N)'	System	24 Apr 2021 12:26:03

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-04-24T07:25:55-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bfda95ca-9e7f-47e1-a38f-83090b7c1244'	System	24 Apr 2021 12:26:03
User entered 'No (N)'	System	24 Apr 2021 12:26:03

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-04-24T07:25:58-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: 'bfda95ca-9e7f-47e1-a38f-83090b7c1244'	System	24 Apr 2021 12:26:03
User entered '24 Apr 2021 07:25:58'	System	24 Apr 2021 12:26:03

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[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 (5aae20e0ce486b4a)', Time: '2021-05-01T00:17:44-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '3ff621c2-b7d0-42d5-add4-236844c7193d'	System	01 May 2021 05:27:31
User entered 'No (N)'	System	01 May 2021 05:27:31

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

Have you been exposed to someone with 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 (5aae20e0ce486b4a)', Time: '2021-05-01T00:17:47-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '3ff621c2-b7d0-42d5-add4-236844c7193d'	System	01 May 2021 05:27:31
User entered 'No (N)'	System	01 May 2021 05:27:31

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-05-01T00:17:50-05:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '3ff621c2-b7d0-42d5-add4-236844c7193d' User entered '01 May 2021 00:17:50'	System	01 May 2021 05:27:31
	System	01 May 2021 05:27:31

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:07:08

US3092176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:07:08
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:07:08

US3092176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:08:16

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 23:48:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-27T10:54:16-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0aea3be6-03a5-461e-9b18-8f57d1f6cbda'	System	27 Feb 2021 16:54:23
User entered 'No (N)'	System	27 Feb 2021 16:54:23

US3092176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:08:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:48:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5aae20e0ce486b4a)', Time: '2021-02-27T10:54:20-06:00', User OID: 'PatientReportedOutcome (US3092176)', ODM File OID: '0aea3be6-03a5-461e-9b18-8f57d1f6cbda' User entered '27 Feb 2021 10:54:20'	System	27 Feb 2021 16:54:23
	System	27 Feb 2021 16:54:23

US3092176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:44:38

US3092176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:44:38

US3092176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:44:38

US3092176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:44:38

US3092176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:44:43

US3092176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	16 Nov 2020 20:44:43

US3092176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:09:10

US3092176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:09:10

US3092176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:09:10

US3092176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:09:10

US3092176

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:09:15

US3092176

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	16 Dec 2020 19:09:15

US3092176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:09:29

US3092176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 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)	21 Jan 2021 08:49:09
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'date of call is correct and out of window ' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 01:10:21
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	21 Jan 2021 01:09:29
User entered '20 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 01:09:29

US3092176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:09:29

US3092176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:09:29

US3092176

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:10:57

US3092176

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	21 Jan 2021 01:10:57

US3092176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:42

US3092176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:42

US3092176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:42

US3092176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:42

US3092176

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:49

US3092176

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	16 Feb 2021 21:52:49

US3092176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:00

US3092176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:00

US3092176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:00

US3092176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'VISIT4'	System	24 Mar 2021 14:34:00

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '22 Mar 2021'	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '10:35'	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '22 Mar 2021 10:35'	System	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '98.6' F	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered 'Oral (Oral)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered empty.	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '102'	(b) (4) Vicki Martinez (b) (4) (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'bpm'	System	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '18'	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'breaths/min'	System	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '150'	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
User entered '89'	Vicki Martinez (b) (4)	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'mmHg'	System	30 Mar 2021 22:02:52

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42

US3092176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42

US3092176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:29

US3092176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:29

US3092176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
Signature has been broken.	Vicki Martinez (b) (4)	30 Mar 2021 23:41:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	30 Mar 2021 23:41:04
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 14:34:47

US3092176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
Signature has been broken.	(b) (4) Vicki Martinez (b) (4)	30 Mar 2021 23:41:04
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	30 Mar 2021 23:41:04
User signature succeeded.	(b) (4) Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:47

US3092176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:38:07
Signature has been broken.	(b) (4) Vicki Martinez (b) (4)	30 Mar 2021 23:41:04
User entered '10:50' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	30 Mar 2021 23:41:04
User signature succeeded.	(b) (4) Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:34:47

US3092176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered '22 Mar 2021 10:50'	System	30 Mar 2021 23:41:04
User entered empty.	System	24 Mar 2021 14:34:47

US3092176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:44:22

US3092176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:39:42
User entered 'I'	System	24 Mar 2021 14:44:22

US3092176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 22:43:42

US3092176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 22:43:42

US3092176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 22:43:42

US3092176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 22:43:42

US3092176

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 22:43:46

US3092176

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 22:43:46

US3092176

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

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:44:34

US3092176

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

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:44:34

US3092176

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

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[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 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Clinic (Clinic)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:44:34

US3092176

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

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:44:34

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[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 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:45:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:04:51

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:45:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:04:51

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Placebo (Placebo)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:54:57
User entered 'Placebo (Placebo)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02
	(b) (4)	

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:54:57
User entered 'Placebo (Placebo)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02
	(b) (4)	

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:02

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '1'	System	14 Jan 2021 19:46:02

US3092176

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

Form: Unblinding

Generated On: 09 Jun 2021 15:08:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'I'	System	14 Jan 2021 19:46:02

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '190.5' cm	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '277.2' lb	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '34.72007'	System	14 Jan 2021 19:49:34
DataPoint set to visible.	System	14 Jan 2021 19:46:02

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '190.5' cm	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '277.2' lb	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '34.72007'	System	14 Jan 2021 19:49:34
DataPoint set to visible.	System	14 Jan 2021 19:46:02

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User accepted default value 'Pre-Dose (PREDOSE)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34
	(b) (4)	

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:05'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '14 Jan 2021 11:05'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '98.2' F	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '93'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'bpm'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '15'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'breaths/min'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '138'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '90'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '190.5' cm	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '277.2' lb	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '34.72007'	System	14 Jan 2021 19:49:34
DataPoint set to visible.	System	14 Jan 2021 19:46:02

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User accepted default value 'Post-Dose (POSTDOSE)'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '12:02'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '14 Jan 2021 12:02'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '98.0' F	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '95'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'bpm'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '16'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'breaths/min'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '144'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '84'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:34

US3092176

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	14 Jan 2021 19:49:34

US3092176

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:43

US3092176

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:49:43

US3092176

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

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:50:51

US3092176

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

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 19:50:51

US3092176

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

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 19:50:51

US3092176

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

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mRNA-1273'	System	14 Jan 2021 19:50:51
DataPoint set to visible.	System	14 Jan 2021 19:46:02

US3092176

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

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:50:51

US3092176

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

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:29'	Marissa Cervenka (b) (4)	14 Jan 2021 19:50:51

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '14 Jan 2021 11:29'	System	14 Jan 2021 19:50:51

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Left Arm (LEFT ARM)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:50:51

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'ONCE'	System	14 Jan 2021 19:50:51

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 19:50:51

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:31

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:31

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:26'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:31

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '14 Jan 2021 11:26'	System	14 Jan 2021 19:46:31

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:47

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:16

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '14 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:47

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '11:24'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:47

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '14 Jan 2021 11:24'	System	14 Jan 2021 19:46:47

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 19:46:53

US3092176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'I'	System	14 Jan 2021 19:46:53

US3092176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 01:07:52

US3092176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 01:07:52

US3092176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 01:07:52

US3092176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 01:07:52

US3092176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 01:10:04

US3092176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'I'	System	22 Jan 2021 01:10:04

US3092176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'I'	System	22 Jan 2021 01:10:04
DataPoint set to visible.	System	22 Jan 2021 01:10:04

US3092176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:39:47

US3092176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).		08 Mar 2021 05:45:58
User signature succeeded.	Valentine Ebu (b) (4)	07 Mar 2021 18:27:32
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'confirmed data correct.. out of window per inclement weather. site was closed.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:51:38
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Mar 2021 23:39:47
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 23:39:47

US3092176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[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 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:39:47

US3092176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'OLD29'	System	01 Mar 2021 23:39:47

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User accepted default value 'Pre-Dose (PREDOSE)'		01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '11:15'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '26 Feb 2021 11:15'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '81'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'bpm'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '14'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'breaths/min'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '150'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '90'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User accepted default value 'Post-Dose (POSTDOSE)'		01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Mar 2021 23:59:21
Query 'Data is required. Please provide.' answered by System	System	01 Mar 2021 23:59:21
data change (Site from System).		
User entered '12:13' reason for change: Data Entry	(b) (4), (b) (6)	01 Mar 2021 23:59:21
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 23:57:30
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '26 Feb 2021 12:13'	System	01 Mar 2021 23:59:21
User entered empty.	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Mar 2021 23:59:35
Query 'Data is required. Please provide.' answered by System	System	01 Mar 2021 23:59:35
data change (Site from System).		
User entered '98.6' F reason for change: Data Entry	(b) (4), (b) (6)	01 Mar 2021 23:59:35
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 23:57:30
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '85'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'bpm'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '17'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'breaths/min'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '140'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '89'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	01 Mar 2021 23:57:30

US3092176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:59:45

US3092176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:59:45

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	02 Mar 2021 00:00:43
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	02 Mar 2021 00:00:43
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	02 Mar 2021 00:00:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

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 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mRNA-1273'	System	02 Mar 2021 00:00:05
DataPoint set to visible.	System	22 Jan 2021 01:10:04

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	02 Mar 2021 00:00:43
User entered '11:43' reason for change: Data Entry Error	System	02 Mar 2021 00:00:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 00:00:43
User entered '11:4' (non-conformant).	System	02 Mar 2021 00:00:05
	(b) (4), (b) (6)	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '26 Feb 2021 11:43'	System	02 Mar 2021 00:00:43
User entered '26 Feb 2021 11:4' (non-conformant).	System	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:00:43
User entered empty.		02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'ONCE'	System	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 00:00:05

US3092176

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:00:49

US3092176

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'I'	System	02 Mar 2021 00:00:49

US3092176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:51:16

US3092176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:51:16

US3092176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:51:16

US3092176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:51:16

US3092176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:51:41

US3092176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'I'	System	09 Mar 2021 00:51:41

US3092176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:50:54

US3092176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebu (b) (4)	28 Mar 2021 01:03:40
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'confirmed, data correct' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 07:47:19
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'confirmed, data correct' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 14:57:58
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 14:50:54
User entered '22 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:50:54

US3092176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[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 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:50:54

US3092176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'OLD57'	System	24 Mar 2021 14:50:54

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '10:35'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '22 Mar 2021 10:35'	System	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '102'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'bpm'	System	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'breaths/min'	System	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '150'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '89'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered 'mmHg'	System	24 Mar 2021 15:00:12

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50

US3092176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50

US3092176

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:01:40

US3092176

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:01:40

US3092176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:03:55

US3092176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:03:55

US3092176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:03:40
User entered '10:50'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:03:55

US3092176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:25:50
User entered '22 Mar 2021 10:50'	System	24 Mar 2021 15:03:55

US3092176

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:08:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Signature has been broken.	Marissa Cervenka (b) (4)	12 Apr 2021 22:19:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	12 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 00:02:29

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:13:17
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered	(b) (4)	13 Apr 2021 18:10:47
'USA-US086-2021-mRNA-1273-P301000015'	System	13 Apr 2021 18:10:47
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 18:10:47

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis, LLT: Pancreatitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Apr 2021 23:00:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 23:00:23
Data point term sent to Coder	System	12 Apr 2021 22:31:44
User entered 'PANCREATITIS'	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '30 Mar 2021'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 22:48:14
User entered 'No (N)' reason for change: Data Entry Error		19 Apr 2021 22:48:14
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Yes (Y)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:21:30
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'CONFIRMED, UPDATE MADE' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 22:48:30
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 22:48:14
User entered '10 Apr 2021' reason for change: Data Entry Error		19 Apr 2021 22:48:14
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).		19 Apr 2021 19:28:21
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 22:32:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 22:32:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	12 Apr 2021 22:32:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 22:30:56
User entered empty.	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	12 Apr 2021 22:31:29
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Apr 2021 22:30:56
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 22:31:29
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Apr 2021 22:31:29
User entered '1' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	12 Apr 2021 22:31:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 22:30:56
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '30 Mar 2021'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '10 Apr 2021'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered 'No (N)'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:17:34
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'CONFIRMED, UPDATE MADE' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:22:41
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:22:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error		22 Apr 2021 18:22:19
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).		19 Apr 2021 19:28:33
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:17:51
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'CONFIRMED, UPDATE MADE' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:22:46
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:22:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error		22 Apr 2021 18:22:19
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).		19 Apr 2021 19:28:43
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

None

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	16 Apr 2021 22:52:27
Signature has been broken.	destiny robinson (b) (4)	16 Apr 2021 22:52:27
	(b) (4)	
User entered '0' reason for change: Data Entry Error	destiny robinson (b) (4)	16 Apr 2021 22:52:27
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	16 Apr 2021 22:52:13
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '1'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
Signature has been broken.	destiny robinson (b) (4)	16 Apr 2021 22:52:13
	(b) (4)	
User entered '1' reason for change: Data Entry Error	destiny robinson (b) (4)	16 Apr 2021 22:52:13
	(b) (4)	
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:21:35
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'CONFIRMED, UPDATE MADE' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 22:48:44
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 22:48:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		19 Apr 2021 22:48:14
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).		19 Apr 2021 19:28:08
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:58:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:58:12
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records have been requested three separate times and have not been received. The three separate attempts were made on 12APR2021, 16 APR2021, and 23APR2021, respectively.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 22:22:19
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Medical records have been requested three separate times and have not been received. The three separate attempts were made on 12APR2021, 16 APR2021, and 23APR2021, respectively.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 22:21:18
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:28:59

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[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. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:28:52
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered empty.	(b) (4) Marissa Cervenka (b) (4)	12 Apr 2021 22:30:56
	(b) (4)	

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 22:30:56

US3092176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:08:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 22:30:56

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:08:16

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:06:28
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:54:04
User closed query 'Per CDM, re-query of system queries on e-diaries: Per Diary Dose 1 (1), Temperature day, Day 5. Per the participant response, medication was taken to treat pain or fever. There was a response “ Advil 200mg x 4 tablets”; per Diary Dose 2 (1), Temperature day, Day 3 – Day 8 – response “Subject took 800mg advil” ; however, there are no CMs recorded. Please update the ConMed eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:09:00
User closed query 'Per CDM : Concomitant medication taken is answered as "yes", kindly update the concomitant medication page appropriately. As per the DQ response on e-dairy the participant has taken medication for pain/Fever. Kindly update ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:08:58
Query 'Per CDM, re-query of system queries on e-diaries: Per Diary Dose 1 (1), Temperature day, Day 5. Per the participant response, medication was taken to treat pain or fever. There was a response “ Advil 200mg x 4 tablets”; per Diary Dose 2 (1), Temperature day, Day 3 – Day 8 – response “Subject took 800mg advil” ; however, there are no CMs recorded. Please update the ConMed eCRF as appropriate.' answered with 'con med log has been updated ' (Site from DM).		16 Feb 2021 17:43:42
Query 'Per CDM : Concomitant medication taken is answered as "yes", kindly update the concomitant medication page appropriately. As per the DQ response on e-dairy the participant has taken medication for pain/Fever. Kindly update ' answered with 'updated' (Site from DM).		16 Feb 2021 17:42:51

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:08:16

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per CDM, re-query of system queries on e-diaries: Per Diary Dose 1 (1), Temperature day, Day 5. Per the participant response, medication was taken to treat pain or fever. There was a response " Advil 200mg x 4 tablets"; per Diary Dose 2 (1), Temperature day, Day 3 – Day 8 – response "Subject took 800mg advil" ; however, there are no CMs recorded. Please update the ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:31:55
User opened query 'Per CDM : Concomitant medication taken is answered as "yes", kindly update the concomitant medication page appropriately. As per the DQ response on e-dairy the participant has taken medication for pain/Fever. Kindly update ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:16:24
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	22 Aug 2020 23:53:00

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
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)	16 Nov 2020 21:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 21:07:46
Data point term sent to Coder	System	16 Nov 2020 21:07:10
User entered 'Flu shot'	(b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'prophylaxis influenza'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:50:26
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	04 Feb 2021 00:19:14
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:37:18
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Heather Jimenez (b) (4)	04 Feb 2021 00:19:06
User entered 'mL (mL)'	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Injection' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 00:19:06
User entered empty.	Heather Jimenez (b) (4)	16 Nov 2020 21:06:34
	(b) (4), (b) (6)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User entered empty.	System	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User entered empty.	System	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:43
User entered empty.	System	16 Nov 2020 21:06:34

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 21:05:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:05:55
Data point term sent to Coder	System	17 Mar 2021 17:42:23
Coding entries removed.	Catina Adams (b) (4) (b) (4)	17 Mar 2021 17:41:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 17:41:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 17:41:46
Data point term sent to Coder	System	17 Mar 2021 17:41:23
Coding entries removed.	Catina Adams (b) (4) (b) (4)	17 Mar 2021 17:40:30

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:53:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:53:50
Data point term sent to Coder	System	16 Nov 2020 21:09:16
User entered 'Advil'	(b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	(b) (4)	25 Mar 2021 01:08:22
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Pain Removed' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Solicited AE' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 10:39:05
User entered 'FEVER(Solicited AE)' reason for change: Data Entry Error	Catina Adams (b) (4)	17 Mar 2021 17:42:28
User entered 'FEVER' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	Catina Adams (b) (4)	17 Mar 2021 17:42:13
Query 'Per DM CLR: Please note that this condition (FEVER) is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' canceled (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that this condition (FEVER) is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	Catina Adams (b) (4)	17 Mar 2021 17:41:56
	(b) (4)	
	Catina Adams (b) (4)	17 Mar 2021 17:40:30
	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 03:41:34
	(b) (4), (b) (6)	29 Jan 2021 03:41:27
	(b) (4), (b) (6)	29 Jan 2021 03:37:56

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:44:26
User entered 'fever or pain'		16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '800'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 17:40:30
User entered 'un UNK 2012'	Catina Adams (b) (4)	16 Nov 2020 21:08:26
	(b) (4)	
	(b) (4), (b) (6)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4)	17 Mar 2021 17:40:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 17:40:30
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 21:08:26
	(b) (4), (b) (6)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
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). User signature succeeded.	(b) (4)	25 Mar 2021 01:09:43
	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
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 'Took for fever after first vaccine.' (Site from DM).	Catina Adams (b) (4)	17 Mar 2021 17:41:31
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 07:44:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User entered empty.	System	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User entered empty.	System	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:53:37
User entered empty.	System	16 Nov 2020 21:08:26

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Mar 2021 22:47:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:39:43
Data point term sent to Coder	System	04 Feb 2021 00:53:13
User entered 'CYCLOBENZAPRINE'	Catina Adams (b) (4) (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Spinal Stenosis'	(b) (4) Catina Adams (b) (4) (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '10'	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'once daily (QD)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Oral (ORAL)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'UN UNK 2017'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:52:57
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 00:52:57

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 00:56:38
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 00:56:38
Data point term sent to Coder	System	04 Feb 2021 00:55:14
User entered 'LISINOPRIL'	Catina Adams (b) (4) (b) (4)	04 Feb 2021 00:54:52

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'HYPERTENSION'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:54:52

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '10'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'once daily (QD)'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'Oral (ORAL)'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'UN UNK 2019'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 00:54:52

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'Yes (Y)'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	04 Feb 2021 00:54:52
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 00:54:52

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 00:54:52

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 00:54:52

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 01:05:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 01:05:46
Data point term sent to Coder	System	04 Feb 2021 01:04:29
User entered 'ADDERALL'	Catina Adams (b) (4)	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'ATTENTION Deficit HYPERACTIVITY DISORDER'	(b) (4) Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '40'	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'once daily (QD)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Oral (ORAL)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'UN UNK 2015'	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:03:55
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 01:03:55

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 01:06:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 01:06:35
Data point term sent to Coder	System	04 Feb 2021 01:05:29
User entered 'Albuterol'	Catina Adams (b) (4)	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'ASTHMA'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'UNK'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'puff (PUFF)'	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'as needed (PRN)'	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'UN UNK 1990'	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'Yes (Y)'	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:05:23
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 01:05:23

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 11:11:44
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 Feb 2021 11:11:44
Data point term sent to Coder	System	04 Feb 2021 01:07:31
User entered 'METFORMIN'	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'TYPE II DIABETIES'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered '500'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'twice daily (BID)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Oral (ORAL)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered empty.	(b) (4) Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'UN Feb 2020'	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'Yes (Y)'	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:07:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 01:07:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 01:15:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 01:15:49
Data point term sent to Coder	System	04 Feb 2021 01:14:36
Data point term sent to Coder	System	04 Feb 2021 01:13:35
User entered 'ZYRTEC (CETIRIZINE)'	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Seasonal Allergies'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '10'	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'once daily (QD)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 01:13:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 01:13:35
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Catina Adams (b) (4)	04 Feb 2021 01:13:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 01:13:20
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'UN UNK 2000'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:13:20
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 01:13:20

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;MAGNESIUM;ZINC GLUCONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 01:17:41
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 01:17:41
Data point term sent to Coder	System	04 Feb 2021 01:16:38
User entered 'Calcium/Magnesium/ZINC'	Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'General Health'	(b) (4) Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'UNK'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'once daily (QD)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Oral (ORAL)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered 'UN Feb 2020'	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	04 Feb 2021 01:15:59
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:47:41
User entered 'No (N)'	(b) (4) Catina Adams (b) (4) (b) (4)	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 01:15:59

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 23:01:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 23:01:59
Data point term sent to Coder Coding entries removed.	System destiny robinson (b) (4)	16 Apr 2021 23:01:22 16 Apr 2021 23:00:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 22:54:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 22:54:57
Data point term sent to Coder User entered 'lantus'	System destiny robinson (b) (4)	16 Apr 2021 22:54:19 16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'diabetes' reason for change: Data Entry Error	destiny robinson (b) (4)	16 Apr 2021 23:00:25
	(b) (4)	
User entered 'pancreatitis'	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '29'	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'IU (IU)'	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'twice daily (BID)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '1 Apr 2021'	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	16 Apr 2021 22:53:46
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 22:53:46

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Apr 2021 13:33:33
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 Apr 2021 13:33:33
Data point term sent to Coder	System	16 Apr 2021 22:55:19
User entered 'clyindomyocin'	destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'pancreatitis'	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '150'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'mg (mg)'	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'three times daily (TID)'	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Oral (ORAL)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '1 Apr 2021'	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	16 Apr 2021 22:54:39
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 22:54:39

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 23:00:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 23:00:57
Data point term sent to Coder	System	16 Apr 2021 23:00:21
User entered 'metoprolol tartrate'	destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	16 Apr 2021 23:00:06
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'hypertension'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '50'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'mg (mg)'	destiny robinson (b) (4)	16 Apr 2021 23:00:06
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'once daily (QD)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Oral (ORAL)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '1 Apr 2021'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	16 Apr 2021 23:00:06
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'Yes (Y)'	destiny robinson (b) (4)	16 Apr 2021 23:00:06
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 23:00:06

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Apr 2021 13:46:27
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 Apr 2021 13:46:27
Data point term sent to Coder	System	16 Apr 2021 23:01:22
User entered 'famotidine'	destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	16 Apr 2021 23:01:10
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'pancreatitis'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '20'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'mg (mg)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'once daily (QD)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Oral (ORAL)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '1 Apr 2021'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 23:01:10

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Apr 2021 14:50:34
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 Apr 2021 14:50:34
Data point term sent to Coder	System	16 Apr 2021 23:29:05
User entered 'methocarbomal'	destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'pancreatitis'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '500'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'mg (mg)'	destiny robinson (b) (4)	16 Apr 2021 23:02:32
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 23:02:32
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'twice daily (BID)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Oral (ORAL)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '1 Apr 2021'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	16 Apr 2021 23:02:32
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 23:02:32

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Apr 2021 13:41:37
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 Apr 2021 13:41:37
Data point term sent to Coder	System	16 Apr 2021 23:29:05
User entered 'diclycomine'	destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'pancreatitis'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '20'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'mg (mg)'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'four times daily (QID)'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'Oral (ORAL)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '1 Apr 2021'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered 'Yes (Y)'	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	16 Apr 2021 23:03:28
	(b) (4)	

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:08:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 23:03:28

US3092176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:08:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:02:23

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'USA-US086-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Valentine'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Ebuh'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered '2701 S Hampton Road, Suite 250'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Dallas'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'TX'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered (b) (6)	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:22:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'US'	(b) (4) System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:55:04
User entered '3'	System	20 Apr 2021 19:22:34
User entered '2'	System	19 Apr 2021 14:13:42
User entered '1'	System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'USA-US086-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Valentine'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Ebuh'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered '2701 S Hampton Road, Suite 250'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Dallas'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'TX'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered (b) (6)	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:22:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'US'	(b) (4) System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:55:04
User entered '3'	System	20 Apr 2021 19:22:34
User entered '2'	System	19 Apr 2021 14:13:42
User entered '1'	System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:08:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered '13/Apr/2021 14:11'	(b) (4) System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:08:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:22:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'USA-US086-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Valentine'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Ebuh'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered '2701 S Hampton Road, Suite 250'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Dallas'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'TX'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered (b) (6)	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:22:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'US'	(b) (4) System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:55:04
User entered '3'	System	20 Apr 2021 19:22:34
User entered '2'	System	19 Apr 2021 14:13:42
User entered '1'	System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:08:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '19/Apr/2021 10:13'	(b) (4) System	19 Apr 2021 14:13:42

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:08:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:22:15
User entered 'I'		19 Apr 2021 14:13:42

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'USA-US086-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Valentine'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Ebuh'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered '2701 S Hampton Road, Suite 250'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Dallas'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'TX'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered (b) (6)	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:22:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'US'	(b) (4) System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:55:04
User entered '3'	System	20 Apr 2021 19:22:34
User entered '2'	System	19 Apr 2021 14:13:42
User entered '1'	System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:08:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '20/Apr/2021 15:22'	(b) (4) System	20 Apr 2021 19:22:34

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:08:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:22:34

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'USA-US086-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Yes (Y)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'No (N)'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Valentine'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Ebuh'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered '2701 S Hampton Road, Suite 250'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'Dallas'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered 'TX'	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:11:28
User entered (b) (6)	System	13 Apr 2021 18:10:47

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:22:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:01:37
User entered 'US'	(b) (4) System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 19:55:04
User entered '3'	System	20 Apr 2021 19:22:34
User entered '2'	System	19 Apr 2021 14:13:42
User entered '1'	System	13 Apr 2021 18:11:36

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:08:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered '22/Apr/2021 12:55'	(b) (4) System	22 Apr 2021 19:55:04

US3092176

Folder: SAE USA-US086-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:08:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:55:04