

US3052380 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:00:44

All time stamps listed in this document are displayed in GMT

US3052380

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

[Participant ID](#)

US3052380

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

US3052380

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SCRN

US3052380

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	52
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

US3052380

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	8 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3052380

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3052380

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Were any significant conditions reported?

Yes ☒

No ☐

US3052380

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Condition	HYPERTENSION
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)	_____

US3052380

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Condition	HYPERLIPIDEMIA
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)	

US3052380

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Condition	BIPOLAR DISORDER
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)	

US3052380

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Condition	SLEEP APNEA
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)	

US3052380

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Condition	RIGHT SHOULDER SURGERY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

US3052380

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Condition	LEFT KNEE SURGERY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3052380

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:15 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:15
Height (<i>xxx.x</i>)	128.5 cm
Weight (<i>xxx.x</i>)	97.1 kg
BMI (<i>xxx.x</i>)	58.80483 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)	

US3052380

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3052380

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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

SELF EMPLOYED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3052380

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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)	False
Other	False
Specify	

US3052380

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	VISIT1

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 145784

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 ☒

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Height	ND - Not Done
Weight	ND - Not Done

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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)	8 SEP 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:15
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)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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)	8 SEP 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 14:39
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 13:56 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 13:56

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

US3052380

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 SEP 2020

Collection time (00:00-23:59)

13:42 (24 HR)

Collection date and time (derived)

8 SEP 2020 13:42

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:40	8 SEP 2020 13:40
Nasopharyngeal Swab 2	No		

US3052380

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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 98.7 °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 True

PC Time Stamp 08 SEP 2020 14:42

PC Open Date & Time 08 SEP 2020 14:16

PC Close Date & Time 08 SEP 2020 16:46

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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 98.1 °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):

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

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

PC Time Stamp 08 SEP 2020 21:13

PC Open Date & Time 08 SEP 2020 17:41

PC Close Date & Time 09 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

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):

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

09 SEP 2020 18:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

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	98.1 °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	10 SEP 2020 22:11
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

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 <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	11 SEP 2020 20:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

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	98.5 °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	13 SEP 2020 08:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

98.6 °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

13 SEP 2020 12:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

08 SEP 2020 14:43

PC Open Date & Time

08 SEP 2020 14:16

PC Close Date & Time

08 SEP 2020 16:46

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

08 SEP 2020 21:13

PC Open Date & Time

08 SEP 2020 17:41

PC Close Date & Time

09 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

09 SEP 2020 18:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

10 SEP 2020 22:12

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

11 SEP 2020 20:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

13 SEP 2020 08:36

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

13 SEP 2020 12:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

14 SEP 2020 20:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 14:44
PC Open Date & Time	08 SEP 2020 14:16
PC Close Date & Time	08 SEP 2020 16:46

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 21:14
PC Open Date & Time	08 SEP 2020 17:41
PC Close Date & Time	09 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

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 ☒

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:54
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

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)

57 of 2185

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 22:12
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

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 ☒

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 20:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

61 of 2185

EAB) (1725)

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 08:37
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

63 of 2185

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:10
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

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 ☒

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 12:00

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3052380

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:00:44

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	15 SEP 2020 12:00
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3052380

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments LEFT VM

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments LEFT VOICEMAIL @ 11:51

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

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)	8 OCT 2020
Time of assessment (00:00-23:59)	10:18 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:18
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:50
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 17:27:04

Generated On: 09 Jun 2021 15:00:44

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) 8 OCT 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 8 OCT 2020 11:20

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

US3052380

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	8 OCT 2020 10:45

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 17:27:04

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:47	8 OCT 2020 10:47
Nasopharyngeal Swab 2	No		

US3052380

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:04

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

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

08 OCT 2020 11:40

PC Close Date & Time

08 OCT 2020 14:10

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 08 OCT 2020 15:05

PC Close Date & Time 09 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 11:40

PC Close Date & Time

08 OCT 2020 14:10

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 15:05

PC Close Date & Time

09 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 11:40

PC Close Date & Time

08 OCT 2020 14:10

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 15:05

PC Close Date & Time

09 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

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)

105 of 2185

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

Yes ☐

PC Time stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

Yes ☐

PC Time stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

Yes ☐

PC Time stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

111 of 2185

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

Yes ☐

PC Time stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

Yes ☐

PC Time stamp

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3052380

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 DEC 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

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 DEC 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 09:20
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)	115 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052380

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 DEC 2020

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

US3052380

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 DEC 2020

Collection time (00:00-23:59)

09:30 (24 HR)

Collection date and time (derived)

23 DEC 2020 09:30

US3052380

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:07

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 16:50:47
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 82
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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

21 JAN 2021 11:50:50

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

30 JAN 2021 14:16:57

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

04 FEB 2021 02:21:01

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

18 FEB 2021 00:01:54

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	25 FEB 2021 01:23:01
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 18:52:39

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

11 MAR 2021 10:54:20

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

18 MAR 2021 09:36:00

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

25 MAR 2021 08:25:36

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

03 APR 2021 08:33:25

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

08 APR 2021 10:41:58

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 <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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 17:11:31

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 03:10:41
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 <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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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°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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	17 OCT 2022 23:59
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US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3052380

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:00:44

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 12:33:01

US3052380

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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

MISSED

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	15:56 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 15:56
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	107 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052380

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3052380

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

16:25 (24 HR)

Collection date and time (derived)

19 MAR 2021 16:25

US3052380

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052380

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:00:44

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"/>

US3052380

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:00:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3052380

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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

Visit date (dd MMM yyyy)	23 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3052380

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

Form: Unblinding

Data signed: (b) (4) 15 Apr 2021 16:34:31

Generated On: 09 Jun 2021 15:00:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	23 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>)	23 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

US3052380

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Height	188 cm
Weight	96 kg
BMI (xxx.x)	27.16161

US3052380

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Height	188 cm
Weight	96 kg
BMI (xxx.x)	27.16161
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 JAN 2021
Time of assessment (00:00-23:59)	12:18 (24 HR)
Vital Signs Date and Time (derived)	23 JAN 2021 12:18
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Height	188 cm
Weight	96 kg
BMI (xxx.x)	27.16161
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 JAN 2021
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	23 JAN 2021 13:41
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 JAN 2021

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

US3052380

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

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

Treatment Date and Time (derived) 23 JAN 2021 13:00

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

US3052380

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 JAN 2021

Collection time (00:00-23:59)

12:54 (24 HR)

Collection date and time (derived)

23 JAN 2021 12:54

US3052380

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 JAN 2021
Collection time (00:00 - 23:59)	12:59
Collection Date and Time (derived)	23 JAN 2021 12:59

US3052380

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

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LVM

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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)	17 FEB 2021
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 09:50
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3052380

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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) 17 FEB 2021

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 11:02

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

What was the frequency of the study treatment dosing? ONCE

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

US3052380

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

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

MISSED

If Contact Not Made, please provide Comments

US3052380

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 17:27:03

Generated On: 09 Jun 2021 15:00:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052380

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:56 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 15:56
Temperature (<i>xxx.x</i>)	37 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	107 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052380

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3052380

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	16:25 (24 HR)
Collection date and time (derived)	19 MAR 2021 16:25

US3052380

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 12:27:37

Generated On: 09 Jun 2021 15:00:44

AEID	USA-US117-2021-MRNA-1273-P30 1000005
Adverse event	HERNEATED DISKS
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)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	19 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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367 of 2185

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 12:27:37

Generated On: 09 Jun 2021 15:00:44

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ON 18 FEB 2021 PATIENT HAD THREE HERNIATED DISKS REMOVED FROM THE NECK AT PINEHURST SURGICAL (b) (6). WAS INPATIENT OVERNIGHT LEFT 19 FEB 2021
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2185

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 12:27:37

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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

Yes ☒

No ☐

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

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication TELMISARTAN
HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 80/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2185

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

	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 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HLD

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

373 of 2185

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication DIVALPROEX SODIUM

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER

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

375 of 2185

EAB) (1725)

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication MAGNESEUM

Prophylaxis Yes ☒
No ☐

Indication VITAMIN

Dose per administration 450

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)

377 of 2185

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2185

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE PAIN/NECK
BACK, SHOULDER PAIN

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2185

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

Name of Medication HARVONI

Prophylaxis Yes ☐
No ☒

Indication HEPATITIS C

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

383 of 2185

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Mar 2021 17:27:02

Generated On: 09 Jun 2021 15:00:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)		
Start date completely unknown	True	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 20:43:16

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:00:44

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

US3052380

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:00:44

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 ☐

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:37:06

Generated On: 09 Jun 2021 15:00:44

SAEID	USA-US117-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:37:06

Generated On: 09 Jun 2021 15:00:44

SAEID	USA-US117-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/MAR/2021 08:22
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

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:37:06

Generated On: 09 Jun 2021 15:00:44

SAEID	USA-US117-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/APR/2021 09:27
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

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:37:06

Generated On: 09 Jun 2021 15:00:44

SAEID	USA-US117-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 10:36
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

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 20:37:06

Generated On: 09 Jun 2021 15:00:44

SAEID	USA-US117-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/APR/2021 11:32
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

US3052380 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052380

Form: Participant Creation

Generated On: 09 Jun 2021 15:00:44

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'US3052380'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:42

US3052380

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:20:51

US3052380

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:43

US3052380

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:51

US3052380

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'SCRN'	System	08 Sep 2020 18:20:51

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1968) recorded on this form does not match with the Year of birth (1986) reported in PPD Central lab for the sample dated 08OCT2020. Please update correct year or else please confirm if Year of Birth (1968) is correct to be updated in GCL records' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 09:29:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1968) recorded on this form does not match with the Year of birth (1986) reported in PPD Central lab for the sample dated 08OCT2020. Please update correct year or else please confirm if Year of Birth (1968) is correct to be updated in GCL records' answered with 'the correct year of birth is 1968' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 13:48:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth (1968) recorded on this form does not match with the Year of birth (1986) reported in PPD Central lab for the sample dated 08OCT2020. Please update correct year or else please confirm if Year of Birth (1968) is correct to be updated in GCL records' (Site from DM).		03 Dec 2020 14:32:34
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:44

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '51'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'YEARS'	System	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '52'	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Male (M)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'I'	Stacey Saldua (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:00:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 13:29:07

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Sep 2020'	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2020'	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 21:42:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:42:53
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	06 Nov 2020 21:42:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 18:21:25
User entered empty.	System	08 Sep 2020 18:21:25
	(b) (4), (b) (6)	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	08 Sep 2020 18:21:25
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	08 Sep 2020 18:21:25
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4)	08 Sep 2020 18:21:25
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:43

US3052380

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:00:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'I'	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:58

US3052380

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:00:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:24:02

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:25:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:25:29
Data point term sent to Coder	System	09 Oct 2020 15:24:40
User entered 'hypertension'	Stacey Saldua (b) (4)	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:24:36

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:26:32
Data point term sent to Coder	System	09 Oct 2020 15:25:41
User entered 'hyperlipidemia'	Stacey Saldua (b) (4)	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:25:11

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per DM CLR: Please review and confirm if CM #3 (DIVALPROEX SODIUM) was given for this MH condition. If yes, reconcile MH term and CM indication so there will be an appropriate match. Update applicable eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:15:21
Query 'Per DM CLR: Please review and confirm if CM #3 (DIVALPROEX SODIUM) was given for this MH condition. If yes, reconcile MH term and CM indication so there will be an appropriate match. Update applicable eCRF as appropriate.' answered with 'review and update' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 18:58:44
User opened query 'Per DM CLR: Please review and confirm if CM #3 (DIVALPROEX SODIUM) was given for this MH condition. If yes, reconcile MH term and CM indication so there will be an appropriate match. Update applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:02:28
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:26:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:26:33
Data point term sent to Coder	System	09 Oct 2020 15:25:43
User entered 'bipolar disorder'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:25:32

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Ischaemic stroke, LLT: Ischemic stroke - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:53:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:53:25
Data point term sent to Coder	System	09 Oct 2020 15:27:46
User entered 'stroke (ischemic)'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:27:04

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:28:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:28:22
Data point term sent to Coder	System	09 Oct 2020 15:27:49
User entered 'hepatitis c'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 15:33:52
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:33
	(b) (4)	

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016' reason for change:	(b) (4)	
Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:33:52
User entered empty.	(b) (4)	
	Stacey Saldua (b) (4)	09 Oct 2020 15:27:33
	(b) (4)	

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:33:52
User entered empty.	System	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:33:52
User entered empty.	System	09 Oct 2020 15:27:33

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:38:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:38:25
Data point term sent to Coder	System	09 Oct 2020 15:37:02
User entered 'sleep apnea'	Stacey Saldua (b) (4)	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2016'	System	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2016'	System	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	09 Oct 2020 15:36:46

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 08:16:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:45:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:45:29
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 15:44:13
User entered 'right shoulder surgery' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:43:39
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 15:38:03
Query 'Data is required. Please complete.' answered with 'review and update' (Site from System).	Stacey Saldua (b) (4)	09 Oct 2020 15:37:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 15:37:20
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:37:20
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 15:36:01
User entered 'sleep apnea'	Stacey Saldua (b) (4)	09 Oct 2020 15:35:43
	(b) (4)	

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	09 Oct 2020 15:43:39
User entered 'UN UNK 2006' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:43:39
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	09 Oct 2020 15:37:20
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:37:20
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	09 Oct 2020 15:35:43
	(b) (4)	

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:35:43

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:43:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 15:43:39
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:43:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:37:20
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:37:20
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 15:35:43
	(b) (4)	

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2006' reason for change:	(b) (4)	
Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:43:39
User entered empty.	(b) (4)	
	Stacey Saldua (b) (4)	09 Oct 2020 15:35:43
	(b) (4)	

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:35:43

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2006'	System	09 Oct 2020 15:43:39
User entered empty.	System	09 Oct 2020 15:37:20
User entered 'Jan 2016'	System	09 Oct 2020 15:35:43

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2006'	System	09 Oct 2020 15:43:39
User entered empty.	System	09 Oct 2020 15:37:20
User entered '2016'	System	09 Oct 2020 15:35:43

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 2006'	System	09 Oct 2020 15:43:39
User entered empty.	System	09 Oct 2020 15:35:43

US3052380

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '2006'	System	09 Oct 2020 15:43:39
User entered empty.	System	09 Oct 2020 15:35:43

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
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)	09 Oct 2020 15:46:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:46:38
Data point term sent to Coder	System	09 Oct 2020 15:45:17
User entered 'left knee surgery'	Stacey Saldua (b) (4)	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 1990'	Stacey Saldua (b) (4)	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 1990'	Stacey Saldua (b) (4)	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 1990'	System	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '1990'	System	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'Jan 1990'	System	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '1990'	System	09 Oct 2020 15:44:15

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 13:39:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 13:39:56
Data point term sent to Coder	System	20 Oct 2020 19:52:16
User entered 'cpap (sleep apnea)'	Stacey Saldua (b) (4)	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'I'	Stacey Saldua (b) (4)	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	20 Oct 2020 19:51:40

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 15:48:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 15:48:43
Data point term sent to Coder	System	05 Feb 2021 15:47:33
User entered 'bilateral knee pain'	(b) (4), (b) (6)	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	05 Feb 2021 15:47:29
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:29

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 15:06:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 15:06:55
Data point term sent to Coder	System	06 Apr 2021 15:06:05
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) NECK PAIN 2) BACK PAIN 3)SHOULDER PAIN. Thank you.	System	06 Apr 2021 15:05:15
' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 15:05:15
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) NECK PAIN 2) BACK PAIN 3)SHOULDER PAIN. Thank you.	(b) (4), (b) (6)	06 Apr 2021 15:05:08
' answered with 'updated' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 15:05:08
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 15:05:08
User entered 'NECK pain' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 15:05:08
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) NECK PAIN 2) BACK PAIN 3)SHOULDER PAIN. Thank you.	Coder Import (b) (4)	30 Mar 2021 12:13:57
' (Site from System).	(b) (4)	19 Mar 2021 17:27:04
User signature succeeded.	Yaa Oppong (b) (4)	05 Feb 2021 15:48:33
Data point term sent to Coder	System	05 Feb 2021 15:47:53
User entered 'neck, back, shoulder pain'	(b) (4), (b) (6)	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	05 Feb 2021 15:47:53
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	05 Feb 2021 15:47:53

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 15:06:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 15:06:55
Data point term sent to Coder	System	06 Apr 2021 15:06:06
User entered 'BACK PAIN'	(b) (4), (b) (6)	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4)	06 Apr 2021 15:05:45
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4)	06 Apr 2021 15:05:45
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:05:45

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 15:06:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 15:06:55
Data point term sent to Coder	System	06 Apr 2021 15:06:06
User entered 'SHOULDER pain'	(b) (4), (b) (6)	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4)	06 Apr 2021 15:06:01
	(b) (4), (b) (6)	

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered empty.	System	06 Apr 2021 15:06:01

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Sep 2020'	Stacey Saldua (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '12:15'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '8 Sep 2020 12:15'	System	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '128.5' cm	(b) (4)	
	Stacey Saldua (b) (4)	09 Oct 2020 15:48:33
	(b) (4)	
DataPoint set to visible.	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '97.1' kg	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:48:33
DataPoint set to visible.	(b) (4) System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User closed query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:20:24
Query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization form. Please reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 15:09:18
User opened query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:03:29
User entered '58.80483'	System	09 Oct 2020 15:48:33
DataPoint set to visible.	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'kg/m2'	System	09 Oct 2020 15:48:33
DataPoint set to visible.	System	08 Sep 2020 18:21:25

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'bpm'	System	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'breaths/min'	System	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'mmHg'	System	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered 'mmHg'	System	09 Oct 2020 15:48:33

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:40:44

US3052380

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	09 Oct 2020 15:49:07
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	09 Oct 2020 15:49:07
User entered '8 Sep 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:49:07
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	09 Oct 2020 15:40:44
User entered '8 Oct 2020'	System	09 Oct 2020 15:40:44
	Stacey Saldua (b) (4)	09 Oct 2020 15:40:44
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:55:03
	(b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

[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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

[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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:55:03
	(b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered empty; reason for change Data Entry Error	System	09 Oct 2020 15:55:03
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 15:55:03
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'self employed' reason for change:	(b) (4)	
Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User entered empty; reason for change Data Entry	(b) (4)	
Error	Stacey Saldua (b) (4)	09 Oct 2020 15:55:03
User entered 'maintenance-military vehicles'	(b) (4)	
	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4)	09 Oct 2020 16:07:58
User entered '1' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 16:07:58
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4)	09 Oct 2020 15:55:03
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

[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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 15:55:03
User entered '1'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18
	(b) (4)	

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:00:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	09 Oct 2020 15:40:18

US3052380

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4)	08 Sep 2020 18:20:40
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Sep 2020'	(b) (4)	08 Sep 2020 18:20:40
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:20:40

US3052380

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'VISIT1'	System	08 Sep 2020 18:20:40

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:53

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '145784'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:53

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	20 Oct 2020 19:16:04
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered by data change (Site from System).	System	20 Oct 2020 19:16:04
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	20 Oct 2020 19:13:59
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:39:53

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

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)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:13:59

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

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)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:13:59

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Signature has been broken.	(b) (4)	06 Apr 2021 15:08:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 15:08:21
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4)	20 Oct 2020 19:13:59
	Stacey Saldua (b) (4)	
	(b) (4)	

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	20 Oct 2020 19:13:59

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	20 Oct 2020 19:16:04
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:13:59

US3052380

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:00:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	06 Nov 2020 21:49:16
DataPoint set to visible.	System	06 Nov 2020 21:42:53
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:39:34

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '12:15'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Sep 2020 12:15'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '98.5' F	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '88'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'bpm'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Oct 2020 19:16:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Oct 2020 19:16:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Stacey Saldua (b) (4)	20 Oct 2020 19:16:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	09 Oct 2020 18:28:41
User entered empty.	Stacey Saldua (b) (4)	09 Oct 2020 18:28:41
	(b) (4)	

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'breaths/min'	System	20 Oct 2020 19:16:45
User entered empty.	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '125'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '77'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '14:39'	Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Sep 2020 14:39'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '98.7' F	Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:28:41
	(b) (4)	

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '86'	Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'bpm'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '14'	Stacey Saldua (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'breaths/min'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '142'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '88'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:28:41

US3052380

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 18:43:17
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	08 Sep 2020 18:21:40
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 18:43:17
User entered '8 Sep 2020'	Stacey Saldua (b) (4)	08 Sep 2020 18:21:40
	(b) (4)	
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4)	08 Sep 2020 18:22:41
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	08 Sep 2020 18:22:41
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

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)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:22:41

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:22:41

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Sep 2020'	(b) (4)	08 Sep 2020 18:22:41
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '13:56'	(b) (4)	08 Sep 2020 18:22:41
	(b) (4), (b) (6)	

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Sep 2020 13:56'	System	08 Sep 2020 18:22:41

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:41

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'ONCE'	System	08 Sep 2020 18:22:41

US3052380

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:22:41

US3052380

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 17:57:54

US3052380

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08sep2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 9-sep-2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:03:02
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08sep2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 9-sep-2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with '8-sep-2020 should be the correct date' (Site from DM).	Stacey Saldua (b) (4)	06 Nov 2020 21:50:47
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08sep2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 9-sep-2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:48:54
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Oct 2020 17:58:17
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		09 Oct 2020 17:58:17
User entered '8 Sep 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 17:58:17
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Oct 2020 17:57:54
User entered '8 Oct 2020'	Stacey Saldua (b) (4)	09 Oct 2020 17:57:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

675 of 2185

US3052380

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '13:42'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:57:54

US3052380

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Sep 2020 13:42'	System	09 Oct 2020 17:58:17
User entered '8 Oct 2020 13:42'	System	09 Oct 2020 17:57:54

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:06:36
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please provide both Accession number and the shipment tracking details in the response. Thank you.' answered with 'sample shipped and results received Accession Number: 1F60HK7 and tracking /ID number 1F652535880' (Site from DM).		19 Feb 2021 16:44:54
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).		10 Feb 2021 06:55:31
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		10 Feb 2021 06:55:31
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'sample shipped and results received Accession Number: 1F60HK7' (Site from DM).		05 Feb 2021 14:10:14

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:15:42
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 08SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 09SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).		24 Nov 2020 12:44:03
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 08SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 09SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with '8-sep-2020 should be the correct date' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	06 Nov 2020 21:51:11
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 08SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 09SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:02:58
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (08SEP2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).		20 Oct 2020 14:02:47

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (08SEP2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:47:27
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Oct 2020 17:58:47
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		09 Oct 2020 17:58:47
User entered '8 Sep 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4)	09 Oct 2020 17:58:47
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
	System	09 Oct 2020 17:58:38
User entered '8 Oct 2020'	Stacey Saldua (b) (4)	09 Oct 2020 17:58:38
	(b) (4)	

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '13:40'	Stacey Saldua (b) (4)	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Sep 2020 13:40'	System	09 Oct 2020 17:58:47
User entered '8 Oct 2020 13:40'	System	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered empty.	System	09 Oct 2020 17:58:38

US3052380

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:58:53

US3052380

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	09 Oct 2020 17:58:53

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:41:40', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c52d8927-f475-4ac2-9ca3-aa5b196be16a'	System	08 Sep 2020 18:42:31
User entered 'Yes (Y)'	System	08 Sep 2020 18:42:31

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:41:49', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c52d8927-f475-4ac2-9ca3-aa5b196be16a' User entered '98.7'	System	08 Sep 2020 18:42:31
	System	08 Sep 2020 18:42:31

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:09', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c52d8927-f475-4ac2-9ca3-aa5b196be16a'	System	08 Sep 2020 18:42:31
User entered 'Yes (Y)'	System	08 Sep 2020 18:42:31

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 05:37:45
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).	Stacey Saldua (b) (4)	18 Feb 2021 17:09:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:19', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c52d8927-f475-4ac2-9ca3-aa5b196be16a'	(b) (4)	
User entered '1'	System	08 Sep 2020 18:42:31
	System	08 Sep 2020 18:42:31
	System	08 Sep 2020 18:42:31

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 05:37:48
User opened query 'Per the participant response, medication was taken to prevent 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).	Stacey Saldua (b) (4)	18 Feb 2021 17:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:19', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c52d8927-f475-4ac2-9ca3-aa5b196be16a'	(b) (4)	
User entered '1'	System	08 Sep 2020 18:42:31
	System	08 Sep 2020 18:42:31
	System	08 Sep 2020 18:42:31

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:26', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c52d8927-f475-4ac2-9ca3-aa5b196be16a'	System	08 Sep 2020 18:42:31
User entered '08 Sep 2020 14:42'	System	08 Sep 2020 18:42:31

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 14:16'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 16:46'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:11:19', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '725e9d82-831e-4878-9643-ecac89979201'	System	09 Sep 2020 01:13:08
User entered 'Yes (Y)'	System	09 Sep 2020 01:13:08

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:12:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '725e9d82-831e-4878-9643-ecac89979201' User entered '98.1'	System	09 Sep 2020 01:13:08

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:12:45', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '725e9d82-831e-4878-9643-ecac89979201'	System	09 Sep 2020 01:13:08
User entered 'Yes (Y)'	System	09 Sep 2020 01:13:08

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 05:38:02
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).	Stacey Saldua (b) (4)	18 Feb 2021 17:09:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:12:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '725e9d82-831e-4878-9643-ecac89979201'	(b) (4)	
User entered '1'	System	09 Sep 2020 01:13:08
	System	09 Sep 2020 01:13:08
	System	09 Sep 2020 01:13:08

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 05:38:07
User opened query 'Per the participant response, medication was taken to prevent 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).	Stacey Saldua (b) (4)	18 Feb 2021 17:09:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:12:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '725e9d82-831e-4878-9643-ecac89979201'	(b) (4)	
User entered '1'	System	09 Sep 2020 01:13:08
	System	09 Sep 2020 01:13:08
	System	09 Sep 2020 01:13:08

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:06', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '725e9d82-831e-4878-9643-ecac89979201'	System	09 Sep 2020 01:13:08
User entered '08 Sep 2020 21:13'	System	09 Sep 2020 01:13:08

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 17:41'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 2'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:17', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9148aabc-382b-4cbc-8788-1deac301af15'	System	09 Sep 2020 22:52:54
User entered 'Yes (Y)'	System	09 Sep 2020 22:52:54

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:29', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9148aabc-382b-4cbc-8788-1deac301af15'	System	09 Sep 2020 22:52:54
User entered '98.3'	System	09 Sep 2020 22:52:54

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:34', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9148aabc-382b-4cbc-8788-1deac301af15'	System	09 Sep 2020 22:52:54
User entered 'Yes (Y)'	System	09 Sep 2020 22:52:54

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4)	19 Feb 2021 04:50:27
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).	Stacey Saldua (b) (4)	18 Feb 2021 17:09:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9148aabc-382b-4cbc-8788-1deac301af15'	(b) (4)	
User entered '1'	System	09 Sep 2020 22:52:54
	System	09 Sep 2020 22:52:54
	System	09 Sep 2020 22:52:54

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:50:30
User opened query 'Per the participant response, medication was taken to prevent 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).	Stacey Saldua (b) (4)	18 Feb 2021 17:09:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9148aabc-382b-4cbc-8788-1deac301af15'	(b) (4)	
User entered '1'	System	09 Sep 2020 22:52:54
	System	09 Sep 2020 22:52:54
	System	09 Sep 2020 22:52:54

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:51', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9148aabc-382b-4cbc-8788-1deac301af15'	System	09 Sep 2020 22:52:54
User entered '09 Sep 2020 18:52'	System	09 Sep 2020 22:52:54

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 3'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:25', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c31d4ea8-2dc4-4c22-8910-b3251c57f741'	System	11 Sep 2020 02:11:45
User entered 'Yes (Y)'	System	11 Sep 2020 02:11:45

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:31', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c31d4ea8-2dc4-4c22-8910-b3251c57f741'	System	11 Sep 2020 02:11:45
User entered '98.1'	System	11 Sep 2020 02:11:45

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:36', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c31d4ea8-2dc4-4c22-8910-b3251c57f741'	System	11 Sep 2020 02:11:45
User entered 'Yes (Y)'	System	11 Sep 2020 02:11:45

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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).		19 Feb 2021 04:50:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	Stacey Saldua (b) (4) (b) (4)	18 Feb 2021 17:14:18
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).	System	11 Sep 2020 02:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:39', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c31d4ea8-2dc4-4c22-8910-b3251c57f741'	System	11 Sep 2020 02:11:45
User entered '1'	System	11 Sep 2020 02:11:45

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:39', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c31d4ea8-2dc4-4c22-8910-b3251c57f741' User entered '0'	System	11 Sep 2020 02:11:45
	System	11 Sep 2020 02:11:45

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c31d4ea8-2dc4-4c22-8910-b3251c57f741'	System	11 Sep 2020 02:11:45
User entered '10 Sep 2020 22:11'	System	11 Sep 2020 02:11:45

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 4'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:00:54', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9875e69a-f406-4a6a-b91c-03c308aa7e32'	System	12 Sep 2020 00:01:17
User entered 'Yes (Y)'	System	12 Sep 2020 00:01:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:01', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9875e69a-f406-4a6a-b91c-03c308aa7e32'	System	12 Sep 2020 00:01:17
User entered '98.7'	System	12 Sep 2020 00:01:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:07', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9875e69a-f406-4a6a-b91c-03c308aa7e32'	System	12 Sep 2020 00:01:17
User entered 'Yes (Y)'	System	12 Sep 2020 00:01:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4)	19 Feb 2021 04:50:45
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).	Stacey Saldua (b) (4)	18 Feb 2021 17:14:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:10', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9875e69a-f406-4a6a-b91c-03c308aa7e32'	(b) (4)	
User entered '1'	System	12 Sep 2020 00:01:17
	System	12 Sep 2020 00:01:17
	System	12 Sep 2020 00:01:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:10', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9875e69a-f406-4a6a-b91c-03c308aa7e32'	System	12 Sep 2020 00:01:17
User entered '0'	System	12 Sep 2020 00:01:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:13', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9875e69a-f406-4a6a-b91c-03c308aa7e32'	System	12 Sep 2020 00:01:17
User entered '11 Sep 2020 20:01'	System	12 Sep 2020 00:01:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 5'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:35:54', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'f9898fcb-a24b-4b52-a731-6bae3001ed96'	System	13 Sep 2020 12:36:17
User entered 'Yes (Y)'	System	13 Sep 2020 12:36:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:05', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'f9898fcb-a24b-4b52-a731-6bae3001ed96'	System	13 Sep 2020 12:36:17
User entered '98.5'	System	13 Sep 2020 12:36:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:09', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'f9898fcb-a24b-4b52-a731-6bae3001ed96'	System	13 Sep 2020 12:36:17
User entered 'Yes (Y)'	System	13 Sep 2020 12:36:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:50:51
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).	Stacey Saldua (b) (4)	18 Feb 2021 17:14:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:12', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'f9898fcb-a24b-4b52-a731-6bae3001ed96'	(b) (4)	
User entered '1'	System	13 Sep 2020 12:36:17
	System	13 Sep 2020 12:36:17
	System	13 Sep 2020 12:36:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:12', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'f9898fcb-a24b-4b52-a731-6bae3001ed96'	System	13 Sep 2020 12:36:17
User entered '0'	System	13 Sep 2020 12:36:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:15', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'f9898fcb-a24b-4b52-a731-6bae3001ed96'	System	13 Sep 2020 12:36:17
User entered '13 Sep 2020 08:36'	System	13 Sep 2020 12:36:17

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 6'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:09:25', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7b90ba3a-4060-496a-85a5-4bdf810efa3f'	System	13 Sep 2020 16:10:12
User entered 'Yes (Y)'	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:09:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7b90ba3a-4060-496a-85a5-4bdf810efa3f'	System	13 Sep 2020 16:10:12
User entered '98.6'	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:09:41', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7b90ba3a-4060-496a-85a5-4bdf810efa3f'	System	13 Sep 2020 16:10:12
User entered 'Yes (Y)'	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
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 'Patient error. Medication was not taken for pain or fever ' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:50:56
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).	Stacey Saldua (b) (4)	18 Feb 2021 17:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:09:58', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7b90ba3a-4060-496a-85a5-4bdf810efa3f'	(b) (4)	
User entered '1'	System	13 Sep 2020 16:10:12
	System	13 Sep 2020 16:10:12
	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:09:58', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7b90ba3a-4060-496a-85a5-4bdf810efa3f' User entered '0'	System	13 Sep 2020 16:10:12
	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:09', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7b90ba3a-4060-496a-85a5-4bdf810efa3f'	System	13 Sep 2020 16:10:12
User entered '13 Sep 2020 12:10'	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 7'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:10:42', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '320f13af-2b19-4c00-b9f5-bf9d6767ed40'	System	15 Sep 2020 00:12:14
User entered 'Yes (Y)'	System	15 Sep 2020 00:12:14

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:11:41', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '320f13af-2b19-4c00-b9f5-bf9d6767ed40'	System	15 Sep 2020 00:12:14
User entered '97.9'	System	15 Sep 2020 00:12:14

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:08', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '320f13af-2b19-4c00-b9f5-bf9d6767ed40'	System	15 Sep 2020 00:12:14
User entered 'No (N)'	System	15 Sep 2020 00:12:14

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:13', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '320f13af-2b19-4c00-b9f5-bf9d6767ed40'	System	15 Sep 2020 00:12:14
User entered '14 Sep 2020 20:12'	System	15 Sep 2020 00:12:14

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:39', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '57f03ac1-9825-47ff-a07b-c7c13e47fdcb'	System	08 Sep 2020 18:43:07
User entered 'None (1)'	System	08 Sep 2020 18:43:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '57f03ac1-9825-47ff-a07b-c7c13e47fdcb'	System	08 Sep 2020 18:43:07
User entered 'No (N)'	System	08 Sep 2020 18:43:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:45', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '57f03ac1-9825-47ff-a07b-c7c13e47fdcb'	System	08 Sep 2020 18:43:07
User entered 'No (N)'	System	08 Sep 2020 18:43:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:42:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '57f03ac1-9825-47ff-a07b-c7c13e47fdcb'	System	08 Sep 2020 18:43:07
User entered 'None (1)'	System	08 Sep 2020 18:43:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:43:05', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '57f03ac1-9825-47ff-a07b-c7c13e47fdcb' User entered '08 Sep 2020 14:43'	System	08 Sep 2020 18:43:07
	System	08 Sep 2020 18:43:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 14:16'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 16:46'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:16', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '58b72be8-f62e-462d-99b4-ccb5430eb074'	System	09 Sep 2020 01:13:55
User entered 'None (1)'	System	09 Sep 2020 01:13:55

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:32', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '58b72be8-f62e-462d-99b4-ccb5430eb074'	System	09 Sep 2020 01:13:55
User entered 'No (N)'	System	09 Sep 2020 01:13:55

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '58b72be8-f62e-462d-99b4-ccb5430eb074'	System	09 Sep 2020 01:13:55
User entered 'No (N)'	System	09 Sep 2020 01:13:55

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:45', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '58b72be8-f62e-462d-99b4-ccb5430eb074'	System	09 Sep 2020 01:13:55
User entered 'None (1)'	System	09 Sep 2020 01:13:55

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:51', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '58b72be8-f62e-462d-99b4-ccb5430eb074'	System	09 Sep 2020 01:13:55
User entered '08 Sep 2020 21:13'	System	09 Sep 2020 01:13:55

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 17:41'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 2'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:52:56', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'ffb91174-e22b-4e22-a041-df2e8650ceb7'	System	09 Sep 2020 22:53:27
User entered 'None (1)'	System	09 Sep 2020 22:53:27

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:02', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'ffb91174-e22b-4e22-a041-df2e8650ceb7'	System	09 Sep 2020 22:53:27
User entered 'No (N)'	System	09 Sep 2020 22:53:27

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:09', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'ffb91174-e22b-4e22-a041-df2e8650ceb7'	System	09 Sep 2020 22:53:27
User entered 'No (N)'	System	09 Sep 2020 22:53:27

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:19', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'ffb91174-e22b-4e22-a041-df2e8650ceb7'	System	09 Sep 2020 22:53:27
User entered 'None (1)'	System	09 Sep 2020 22:53:27

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:25', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'ffb91174-e22b-4e22-a041-df2e8650ceb7'	System	09 Sep 2020 22:53:27
User entered '09 Sep 2020 18:53'	System	09 Sep 2020 22:53:27

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 3'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:50', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a8da933f-ca52-4279-ba19-7705db0824b7'	System	11 Sep 2020 02:12:07
User entered 'None (1)'	System	11 Sep 2020 02:12:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:55', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a8da933f-ca52-4279-ba19-7705db0824b7'	System	11 Sep 2020 02:12:07
User entered 'No (N)'	System	11 Sep 2020 02:12:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:11:58', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a8da933f-ca52-4279-ba19-7705db0824b7'	System	11 Sep 2020 02:12:07
User entered 'No (N)'	System	11 Sep 2020 02:12:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:01', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a8da933f-ca52-4279-ba19-7705db0824b7'	System	11 Sep 2020 02:12:07
User entered 'None (1)'	System	11 Sep 2020 02:12:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:03', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a8da933f-ca52-4279-ba19-7705db0824b7'	System	11 Sep 2020 02:12:07
User entered '10 Sep 2020 22:12'	System	11 Sep 2020 02:12:07

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 4'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:17', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e530705d-c048-49b1-a831-41f7db0de108'	System	12 Sep 2020 00:01:31
User entered 'None (1)'	System	12 Sep 2020 00:01:31

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:20', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e530705d-c048-49b1-a831-41f7db0de108'	System	12 Sep 2020 00:01:31
User entered 'No (N)'	System	12 Sep 2020 00:01:31

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:23', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e530705d-c048-49b1-a831-41f7db0de108'	System	12 Sep 2020 00:01:31
User entered 'No (N)'	System	12 Sep 2020 00:01:31

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:26', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e530705d-c048-49b1-a831-41f7db0de108'	System	12 Sep 2020 00:01:31
User entered 'None (1)'	System	12 Sep 2020 00:01:31

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:29', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e530705d-c048-49b1-a831-41f7db0de108'	System	12 Sep 2020 00:01:31
User entered '11 Sep 2020 20:01'	System	12 Sep 2020 00:01:31

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 5'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:21', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c8462929-8c08-4fd3-a61e-bb6993c672ef'	System	13 Sep 2020 12:36:36
User entered 'None (1)'	System	13 Sep 2020 12:36:36

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:24', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c8462929-8c08-4fd3-a61e-bb6993c672ef'	System	13 Sep 2020 12:36:36
User entered 'No (N)'	System	13 Sep 2020 12:36:36

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:26', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c8462929-8c08-4fd3-a61e-bb6993c672ef'	System	13 Sep 2020 12:36:36
User entered 'No (N)'	System	13 Sep 2020 12:36:36

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:31', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c8462929-8c08-4fd3-a61e-bb6993c672ef'	System	13 Sep 2020 12:36:36
User entered 'None (1)'	System	13 Sep 2020 12:36:36

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:33', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'c8462929-8c08-4fd3-a61e-bb6993c672ef'	System	13 Sep 2020 12:36:36
User entered '13 Sep 2020 08:36'	System	13 Sep 2020 12:36:36

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 6'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:14', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'fc3eeda3-324c-435e-950a-e51db1ae5927'	System	13 Sep 2020 16:10:35
User entered 'None (1)'	System	13 Sep 2020 16:10:35

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:17', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'fc3eeda3-324c-435e-950a-e51db1ae5927'	System	13 Sep 2020 16:10:35
User entered 'No (N)'	System	13 Sep 2020 16:10:35

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:21', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'fc3eeda3-324c-435e-950a-e51db1ae5927'	System	13 Sep 2020 16:10:35
User entered 'No (N)'	System	13 Sep 2020 16:10:35

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:28', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'fc3eeda3-324c-435e-950a-e51db1ae5927'	System	13 Sep 2020 16:10:35
User entered 'None (1)'	System	13 Sep 2020 16:10:35

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:30', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'fc3eeda3-324c-435e-950a-e51db1ae5927'	System	13 Sep 2020 16:10:35
User entered '13 Sep 2020 12:10'	System	13 Sep 2020 16:10:35

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 7'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:19', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '09216c5c-09df-47e7-8d9e-77582bea4132'	System	15 Sep 2020 00:12:37
User entered 'None (1)'	System	15 Sep 2020 00:12:37

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:23', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '09216c5c-09df-47e7-8d9e-77582bea4132'	System	15 Sep 2020 00:12:37
User entered 'No (N)'	System	15 Sep 2020 00:12:37

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:28', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '09216c5c-09df-47e7-8d9e-77582bea4132'	System	15 Sep 2020 00:12:37
User entered 'No (N)'	System	15 Sep 2020 00:12:37

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:31', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '09216c5c-09df-47e7-8d9e-77582bea4132'	System	15 Sep 2020 00:12:37
User entered 'None (1)'	System	15 Sep 2020 00:12:37

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:33', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '09216c5c-09df-47e7-8d9e-77582bea4132'	System	15 Sep 2020 00:12:37
User entered '14 Sep 2020 20:12'	System	15 Sep 2020 00:12:37

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:43:11', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'None (0)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:43:14', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'None (0)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:43:17', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'None (0)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:44:16', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'None (0)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:44:19', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'None (0)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:44:22', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'None (0)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:44:28', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered 'No (N)'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T14:44:31', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '3eaaef33-e57c-4d39-b502-727f4ed30e88'	System	08 Sep 2020 18:44:33
User entered '08 Sep 2020 14:44'	System	08 Sep 2020 18:44:33

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 14:16'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 16:46'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:13:57', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'None (0)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:00', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'None (0)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:03', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'None (0)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:15', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'Some interference with activity (2)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:18', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'None (0)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:20', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'None (0)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:29', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered 'No (N)'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-08T21:14:32', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '9ae8d087-60f7-44a0-9e8a-aec6a1f9d7fe'	System	09 Sep 2020 01:14:37
User entered '08 Sep 2020 21:14'	System	09 Sep 2020 01:14:37

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Sep 2020 17:41'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 2'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:32', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'None (0)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:35', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'None (0)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'None (0)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:46', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'None (0)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:50', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'None (0)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:53:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'None (0)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:54:00', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered 'No (N)'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-09T18:54:03', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6c49930c-fbfc-481f-bfc1-25b690fb2663'	System	09 Sep 2020 22:54:08
User entered '09 Sep 2020 18:54'	System	09 Sep 2020 22:54:08

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 3'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:08', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'None (0)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:11', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'None (0)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:16', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'None (0)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:25', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'No interference with activity (1)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:27', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'None (0)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:30', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'None (0)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered 'No (N)'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-10T22:12:41', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd3c44357-16e7-4b3b-b143-c875811740cb'	System	11 Sep 2020 02:12:45
User entered '10 Sep 2020 22:12'	System	11 Sep 2020 02:12:45

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 4'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:35', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'None (0)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:37', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'None (0)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:40', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'None (0)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:44', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'No interference with activity (1)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:47', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'None (0)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:50', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'None (0)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered 'No (N)'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-11T20:01:56', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '452064f3-5626-424c-be21-b571abbf9229'	System	12 Sep 2020 00:01:59
User entered '11 Sep 2020 20:01'	System	12 Sep 2020 00:01:59

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 5'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:39', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'None (0)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'None (0)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:56', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'None (0)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:36:54', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'No interference with activity (1)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:37:00', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'None (0)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:37:03', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'None (0)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:37:06', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered 'No (N)'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T08:37:08', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '4e2a47a5-3eff-40bb-822c-1cc46786f4cb'	System	13 Sep 2020 12:37:11
User entered '13 Sep 2020 08:37'	System	13 Sep 2020 12:37:11

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 6'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:37', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'None (0)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:40', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'None (0)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'None (0)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:45', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'No interference with activity (1)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:50', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'None (0)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'None (0)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:57', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered 'No (N)'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-13T12:10:59', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '8bf13580-6bb9-49b2-bca1-1884671823f9'	System	13 Sep 2020 16:11:03
User entered '13 Sep 2020 12:10'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 7'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'None (0)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:40', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'None (0)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:42', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'None (0)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:46', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'No interference with activity (1)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:47', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'None (0)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:49', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'None (0)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered 'No (N)'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-14T20:12:55', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '7bb9ff8f-ad2d-406c-910d-c1fcfadff3c0'	System	15 Sep 2020 00:12:56
User entered '14 Sep 2020 20:12'	System	15 Sep 2020 00:12:56

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	13 Sep 2020 16:11:03
User entered 'Day 8'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:00:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-15T12:00:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'cabbd7b9-f853-4b62-bd71-bad9588aa1f2'	System	15 Sep 2020 16:01:25
User entered 'None (0)'	System	15 Sep 2020 16:01:25

US3052380

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-15T12:00:46', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'cabbd7b9-f853-4b62-bd71-bad9588aa1f2'	System	15 Sep 2020 16:01:25
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 16:01:25

US3052380

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 16:11:03

US3052380

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	13 Sep 2020 16:10:12
User entered 'Day 8'	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-15T12:00:51', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a026e5d1-6ed3-406c-839b-a97976f47431'	System	15 Sep 2020 16:01:46
User entered 'No (N)'	System	15 Sep 2020 16:01:46

US3052380

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-09-15T12:00:54', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a026e5d1-6ed3-406c-839b-a97976f47431'	System	15 Sep 2020 16:01:46
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 16:01:46

US3052380

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 16:10:12

US3052380

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 16:10:12

US3052380

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:59:37

US3052380

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '17 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:59:37

US3052380

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	Stacey Saldua (b) (4)	09 Oct 2020 17:59:37

US3052380

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'left vm'	Stacey Saldua (b) (4)	09 Oct 2020 17:59:37

US3052380

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 17:59:42

US3052380

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	09 Oct 2020 17:59:42

US3052380

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:04:32

US3052380

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
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).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:12:40
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 'date is correct as entered' (Site from System).	amy sheets (b) (4) (b) (4)	09 Nov 2020 16:37:35
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	09 Oct 2020 18:04:32
User entered '9 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:04:32

US3052380

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4)	09 Oct 2020 18:04:32

US3052380

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	09 Oct 2020 18:04:32

US3052380

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 18:04:58

US3052380

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	09 Oct 2020 18:04:58

US3052380

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 18:06:56

US3052380

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '30 Sep 2020'	Stacey Saldua (b) (4)	09 Oct 2020 18:06:56

US3052380

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	Stacey Saldua (b) (4)	09 Oct 2020 18:06:56

US3052380

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'left voicemail @ 11:51'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:06:56

US3052380

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	09 Oct 2020 18:07:05

US3052380

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	09 Oct 2020 18:07:05

US3052380

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:07:56

US3052380

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '8 Oct 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:07:56

US3052380

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Clinic (Clinic)'	Stacey Saldua (b) (4)	09 Oct 2020 18:07:56

US3052380

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'VISIT2'	System	09 Oct 2020 18:07:56

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '8 Oct 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '10:18'	Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Oct 2020 10:18'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '98.7' F	Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '101'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'bpm'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '16'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'breaths/min'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '147'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '83'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '8 Oct 2020'	(b) (4) Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '11:50'	Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Oct 2020 11:50'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '98.3' F	Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '94'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'bpm'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '16'	Stacey Saldua (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'breaths/min'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '153'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '90'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	09 Oct 2020 18:13:32

US3052380

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:13:51

US3052380

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '8 Oct 2020'	Stacey Saldua (b) (4)	09 Oct 2020 18:13:51

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

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)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Oct 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '11:20'	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Oct 2020 11:20'	System	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Left Arm (LEFT ARM)'	Stacey Saldua (b) (4)	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'ONCE'	System	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 19:18:44

US3052380

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:44:58

US3052380

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '8 Oct 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:44:58

US3052380

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '10:45'	Stacey Saldua (b) (4)	09 Oct 2020 18:44:58

US3052380

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Oct 2020 10:45'	System	09 Oct 2020 18:44:58

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:00:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Oct 2020'	Stacey Saldua (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '10:47'	Stacey Saldua (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '8 Oct 2020 10:47'	System	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered empty.	System	09 Oct 2020 18:45:24

US3052380

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	09 Oct 2020 18:45:52

US3052380

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	09 Oct 2020 18:45:52

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 11:40'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 14:10'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 15:05'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 2'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 3'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 4'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 5'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 6'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 7'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 11:40'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 14:10'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 15:05'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 2'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 3'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 4'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 5'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 6'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 7'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 11:40'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 14:10'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '08 Oct 2020 15:05'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 2'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '09 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 3'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '10 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 4'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '11 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 5'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '12 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 6'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '13 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
Data entry locked.	System	20 Oct 2020 19:18:44
User entered 'Day 7'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

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)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '14 Oct 2020 12:00'	System	20 Oct 2020 19:18:44

US3052380

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:00:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:38:38
User entered '15 Oct 2020 11:59'	System	20 Oct 2020 19:18:44

US3052380

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:20:26

US3052380

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '15 Oct 2020'	Stacey Saldua (b) (4)	20 Oct 2020 19:20:26

US3052380

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4)	20 Oct 2020 19:20:26

US3052380

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	20 Oct 2020 19:20:26

US3052380

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:20:44

US3052380

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	20 Oct 2020 19:20:44

US3052380

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:23:19

US3052380

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Oct 2020'	Avia McClain-Stocker	26 Oct 2020 12:23:19

US3052380

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 12:23:19

US3052380

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 12:23:19

US3052380

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:21:08

US3052380

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	20 Oct 2020 19:21:08

US3052380

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	06 Nov 2020 21:17:43
User entered 'No (N)' reason for change: Data Entry Error	System	06 Nov 2020 21:17:43
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	Stacey Saldua (b) (4)	06 Nov 2020 21:17:24
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 21:17:24

US3052380

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	06 Nov 2020 21:17:24

US3052380

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) Stacey Saldua (b) (4)	06 Nov 2020 21:17:24

US3052380

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	06 Nov 2020 21:17:24

US3052380

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:21:17

US3052380

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	20 Oct 2020 19:21:17

US3052380

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	29 Dec 2020 13:12:23
	(b) (4)	

US3052380

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 06:07:55
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'confirmed dates' (Site from System).	Avia McClain-Stocker (b) (4)	29 Dec 2020 13:12:32
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Dec 2020 13:12:23
User entered '23 Dec 2020'	Avia McClain-Stocker (b) (4)	29 Dec 2020 13:12:23

US3052380

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Clinic (Clinic)'	Avia McClain-Stocker (b) (4)	29 Dec 2020 13:12:23

US3052380

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'VISIT3'	System	29 Dec 2020 13:12:23

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '09:20'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '23 Dec 2020 09:20'	System	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	29 Dec 2020 14:09:17
User entered '98.6' F reason for change: Data Entry Error	System	29 Dec 2020 14:09:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 14:09:07
User entered '98.6' (non-conformant).	System	29 Dec 2020 14:09:07
	(b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '115'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'bpm'	System	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'breaths/min'	System	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '142'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '96'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'mmHg'	System	29 Dec 2020 14:09:07

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53

US3052380

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53

US3052380

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:29

US3052380

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:29

US3052380

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:59

US3052380

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Sample dated 23 DEC 2020 is reported under Visit 3 Day 57 visit in EDC, however the same Immunogenicity sample is missing in PPD. Please kindly update Preclarus accordingly and confirm the accession number, tracking number with shipment date in the response as still missing in the PPD. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:27:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Sample dated 23 DEC 2020 is reported under Visit 3 Day 57 visit in EDC, however the same Immunogenicity sample is missing in PPD. Please kindly update Preclarus accordingly and confirm the accession number, tracking number with shipment date in the response as still missing in the PPD. Thank you' answered with 'PPD updated with appropriate samples' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:52:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: RQ: Sample dated 23 DEC 2020 is reported under Visit 3 Day 57 visit in EDC, however the same Immunogenicity sample is missing in PPD. Please kindly update Preclarus accordingly and confirm the accession number, tracking number with shipment date in the response as still missing in the PPD. Thank you' (Site from DM).		11 Mar 2021 08:22:03
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23DEC2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		11 Mar 2021 08:22:03

US3052380

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23DEC2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'samples are at PPD under requisition barcode ID 1F619580451 no accession # available ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:11:25
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23DEC2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		06 Jan 2021 12:21:24
User entered '23 Dec 2020'		29 Dec 2020 14:09:59

US3052380

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '09:30'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:09:59

US3052380

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered '23 Dec 2020 09:30'	System	29 Dec 2020 14:09:59

US3052380

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:02:35

US3052380

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	09 Dec 2020 16:02:35

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 64'	System	08 Sep 2020 18:22:41

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Please 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Please 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Please 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25
Data entry locked.	System	08 Sep 2020 18:22:41
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 18:22:41

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25
Data entry locked.	System	08 Sep 2020 18:22:41
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25
Data entry locked.	System	08 Sep 2020 18:22:41
User entered 'Day 71'	System	08 Sep 2020 18:22:41

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Please 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Please 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Please 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)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25
Data entry locked.	System	08 Sep 2020 18:22:41
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 18:22:41

US3052380

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:10:25
Data entry locked.	System	08 Sep 2020 18:22:41
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 18:22:41

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (84df6ebc313e6965)', Time: '2020-11-20T16:50:33', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6933291d-145e-479e-af0e-fff096fada4a'	System	20 Nov 2020 21:51:08
User entered 'No (N)'	System	20 Nov 2020 21:51:08

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (84df6ebc313e6965)', Time: '2020-11-20T16:50:44', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6933291d-145e-479e-af0e-fff096fada4a'	System	20 Nov 2020 21:51:08
User entered 'No (N)'	System	20 Nov 2020 21:51:08

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84df6ebc313e6965)', Time: '2020-11-20T16:50:47', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '6933291d-145e-479e-af0e-fff096fada4a'	System	20 Nov 2020 21:51:08
User entered '20 Nov 2020 16:50:47'	System	20 Nov 2020 21:51:08

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (952e8622e80bc56e)', Time: '2021-01-21T11:50:33', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd933b24b-51c9-4057-8dd1-a74edf686d6c'	System	21 Jan 2021 16:50:55
User entered 'No (N)'	System	21 Jan 2021 16:50:55

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Have you been exposed to someone with 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 (952e8622e80bc56e)', Time: '2021-01-21T11:50:38', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd933b24b-51c9-4057-8dd1-a74edf686d6c'	System	21 Jan 2021 16:50:55
User entered 'No (N)'	System	21 Jan 2021 16:50:55

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (952e8622e80bc56e)', Time: '2021-01-21T11:50:50', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'd933b24b-51c9-4057-8dd1-a74edf686d6c'	System	21 Jan 2021 16:50:55
User entered '21 Jan 2021 11:50:50'	System	21 Jan 2021 16:50:55

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (952e8622e80bc56e)', Time: '2021-01-30T14:16:43', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '25b08b14-a11e-429d-8ab4-04994aa170f8'	System	30 Jan 2021 19:16:59
User entered 'No (N)'	System	30 Jan 2021 19:16:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (952e8622e80bc56e)', Time: '2021-01-30T14:16:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '25b08b14-a11e-429d-8ab4-04994aa170f8'	System	30 Jan 2021 19:16:59
User entered 'No (N)'	System	30 Jan 2021 19:16:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (952e8622e80bc56e)', Time: '2021-01-30T14:16:57', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '25b08b14-a11e-429d-8ab4-04994aa170f8'	System	30 Jan 2021 19:16:59
User entered '30 Jan 2021 14:16:57'	System	30 Jan 2021 19:16:59

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (952e8622e80bc56e)', Time: '2021-02-04T02:20:48', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '74769080-b886-4ff8-be8e-0915850542c6'	System	04 Feb 2021 07:21:04
User entered 'No (N)'	System	04 Feb 2021 07:21:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Have you been exposed to someone with 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 (952e8622e80bc56e)', Time: '2021-02-04T02:20:57', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '74769080-b886-4ff8-be8e-0915850542c6'	System	04 Feb 2021 07:21:04
User entered 'No (N)'	System	04 Feb 2021 07:21:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (952e8622e80bc56e)', Time: '2021-02-04T02:21:01', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '74769080-b886-4ff8-be8e-0915850542c6'	System	04 Feb 2021 07:21:04
User entered '04 Feb 2021 02:21:01'	System	04 Feb 2021 07:21:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-02-18T00:01:26', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e55a5153-801a-4106-a5cd-90eb26ba670b'	System	18 Feb 2021 05:03:50
User entered 'No (N)'	System	18 Feb 2021 05:03:50

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-02-18T00:01:42', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e55a5153-801a-4106-a5cd-90eb26ba670b'	System	18 Feb 2021 05:03:50
User entered 'No (N)'	System	18 Feb 2021 05:03:50

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-02-18T00:01:54', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'e55a5153-801a-4106-a5cd-90eb26ba670b'	System	18 Feb 2021 05:03:50
User entered '18 Feb 2021 00:01:54'	System	18 Feb 2021 05:03:50

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-02-25T01:22:28', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '84763c50-7bb1-4597-9c8d-a598a488022d'	System	25 Feb 2021 06:23:04
User entered 'Yes (Y)'	System	25 Feb 2021 06:23:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-02-25T01:22:34', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '84763c50-7bb1-4597-9c8d-a598a488022d'	System	25 Feb 2021 06:23:04
User entered 'No (N)'	System	25 Feb 2021 06:23:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-02-25T01:22:40', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '84763c50-7bb1-4597-9c8d-a598a488022d'	System	25 Feb 2021 06:23:04
User entered 'No (N)'	System	25 Feb 2021 06:23:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-02-25T01:22:52', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '84763c50-7bb1-4597-9c8d-a598a488022d'	System	25 Feb 2021 06:23:04
User entered 'No (N)'	System	25 Feb 2021 06:23:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-02-25T01:23:01', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '84763c50-7bb1-4597-9c8d-a598a488022d'	System	25 Feb 2021 06:23:04
User entered '25 Feb 2021 01:23:01'	System	25 Feb 2021 06:23:04

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-03-06T18:52:00', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '23eb7113-3bc2-4c8a-ab79-ad1ef9a6534d'	System	06 Mar 2021 23:52:43
User entered 'No (N)'	System	06 Mar 2021 23:52:43

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-03-06T18:52:34', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '23eb7113-3bc2-4c8a-ab79-ad1ef9a6534d'	System	06 Mar 2021 23:52:43
User entered 'No (N)'	System	06 Mar 2021 23:52:43

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-03-06T18:52:39', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '23eb7113-3bc2-4c8a-ab79-ad1ef9a6534d'	System	06 Mar 2021 23:52:43
User entered '06 Mar 2021 18:52:39'	System	06 Mar 2021 23:52:43

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-03-11T10:54:03', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '739d40c4-a9c5-48fd-94c9-7e11c190cd3c'	System	11 Mar 2021 15:54:24
User entered 'No (N)'	System	11 Mar 2021 15:54:24

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-03-11T10:54:16', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '739d40c4-a9c5-48fd-94c9-7e11c190cd3c'	System	11 Mar 2021 15:54:24
User entered 'No (N)'	System	11 Mar 2021 15:54:24

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-03-11T10:54:20', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '739d40c4-a9c5-48fd-94c9-7e11c190cd3c'	System	11 Mar 2021 15:54:24
User entered '11 Mar 2021 10:54:20'	System	11 Mar 2021 15:54:24

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-03-18T09:35:52', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '73899949-7c2e-4ede-9a14-450f2f689e52'	System	18 Mar 2021 13:36:05
User entered 'No (N)'	System	18 Mar 2021 13:36:05

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-03-18T09:35:56', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '73899949-7c2e-4ede-9a14-450f2f689e52'	System	18 Mar 2021 13:36:05
User entered 'No (N)'	System	18 Mar 2021 13:36:05

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-03-18T09:36:00', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '73899949-7c2e-4ede-9a14-450f2f689e52'	System	18 Mar 2021 13:36:05
User entered '18 Mar 2021 09:36:00'	System	18 Mar 2021 13:36:05

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-03-25T08:25:23', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '13d84f2b-7661-4e6e-b0d6-b58de09d337a'	System	25 Mar 2021 12:25:40
User entered 'No (N)'	System	25 Mar 2021 12:25:40

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-03-25T08:25:32', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '13d84f2b-7661-4e6e-b0d6-b58de09d337a'	System	25 Mar 2021 12:25:40
User entered 'No (N)'	System	25 Mar 2021 12:25:40

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-03-25T08:25:36', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '13d84f2b-7661-4e6e-b0d6-b58de09d337a'	System	25 Mar 2021 12:25:40
User entered '25 Mar 2021 08:25:36'	System	25 Mar 2021 12:25:40

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-04-03T08:33:16', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '5fcc68da-4942-4d33-96c4-d330999b1d1b'	System	03 Apr 2021 12:33:29
User entered 'No (N)'	System	03 Apr 2021 12:33:29

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-04-03T08:33:22', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '5fcc68da-4942-4d33-96c4-d330999b1d1b'	System	03 Apr 2021 12:33:29
User entered 'No (N)'	System	03 Apr 2021 12:33:29

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-04-03T08:33:25', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '5fcc68da-4942-4d33-96c4-d330999b1d1b'	System	03 Apr 2021 12:33:29
User entered '03 Apr 2021 08:33:25'	System	03 Apr 2021 12:33:29

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-04-08T10:41:53', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '1827170d-8045-4082-bacc-d306cccff443'	System	08 Apr 2021 14:42:03
User entered 'No (N)'	System	08 Apr 2021 14:42:03

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-04-08T10:41:55', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '1827170d-8045-4082-bacc-d306cccff443'	System	08 Apr 2021 14:42:03
User entered 'No (N)'	System	08 Apr 2021 14:42:03

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-04-08T10:41:58', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '1827170d-8045-4082-bacc-d306ccccff443'	System	08 Apr 2021 14:42:03
User entered '08 Apr 2021 10:41:58'	System	08 Apr 2021 14:42:03

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-04-22T17:11:24', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '824f44dd-ba90-4f61-a986-274e343fe8c5'	System	22 Apr 2021 21:11:36
User entered 'No (N)'	System	22 Apr 2021 21:11:36

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-04-22T17:11:28', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '824f44dd-ba90-4f61-a986-274e343fe8c5'	System	22 Apr 2021 21:11:36
User entered 'No (N)'	System	22 Apr 2021 21:11:36

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-04-22T17:11:31', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '824f44dd-ba90-4f61-a986-274e343fe8c5'	System	22 Apr 2021 21:11:36
User entered '22 Apr 2021 17:11:31'	System	22 Apr 2021 21:11:36

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[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 (edd6d7ba813415e5)', Time: '2021-04-29T03:10:01', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '40e6cc95-f4ce-4dbd-8705-6ebd9c6adb92'	System	29 Apr 2021 07:10:45
User entered 'No (N)'	System	29 Apr 2021 07:10:45

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

Have you been exposed to someone with 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 (edd6d7ba813415e5)', Time: '2021-04-29T03:10:14', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '40e6cc95-f4ce-4dbd-8705-6ebd9c6adb92'	System	29 Apr 2021 07:10:45
User entered 'No (N)'	System	29 Apr 2021 07:10:45

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-04-29T03:10:41', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: '40e6cc95-f4ce-4dbd-8705-6ebd9c6adb92'	System	29 Apr 2021 07:10:45
User entered '29 Apr 2021 03:10:41'	System	29 Apr 2021 07:10:45

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:10:25

US3052380

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:00:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:25
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:10:25

US3052380

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:00:44

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)	04 May 2021 03:48:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-02-27T12:32:50', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a189f40d-0f32-4749-8553-bd7a0ae62b3d'	System	27 Feb 2021 17:33:06
User entered 'No (N)'	System	27 Feb 2021 17:33:06

US3052380

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:00:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:48:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (edd6d7ba813415e5)', Time: '2021-02-27T12:33:01', User OID: 'PatientReportedOutcome (US3052380)', ODM File OID: 'a189f40d-0f32-4749-8553-bd7a0ae62b3d'	System	27 Feb 2021 17:33:06
User entered '27 Feb 2021 12:33:01'	System	27 Feb 2021 17:33:06

US3052380

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:02:54

US3052380

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:02:54

US3052380

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:02:54

US3052380

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:02:54

US3052380

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	04 Jan 2021 00:40:42
	(b) (4)	

US3052380

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:19:53
User entered 'I'	System	04 Jan 2021 00:40:42

US3052380

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	16 Mar 2021 00:02:25
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	15 Mar 2021 15:41:33
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 15:41:33

US3052380

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 15:41:33

US3052380

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty; reason for change Data Entry Error	(b) (4)	
	amy sheets (b) (4)	16 Mar 2021 00:02:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	15 Mar 2021 15:41:33

US3052380

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'missed'	(b) (4), (b) (6)	15 Mar 2021 15:41:33

US3052380

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:28:32

US3052380

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User entered 'I'	System	09 Mar 2021 16:28:32

US3052380

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:41:55

US3052380

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:41:55

US3052380

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:41:55

US3052380

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 15:41:55

US3052380

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:28:56

US3052380

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User entered 'I'	System	09 Mar 2021 16:28:56

US3052380

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:29:40

US3052380

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:29:40

US3052380

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:26:14
User entered 'Contact Not Made (CONTACT NOT MADE)'		09 Mar 2021 16:29:40

US3052380

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	(b) (4)	19 Mar 2021 17:27:04
User entered empty; reason for change Data Entry Error	Yaa Oppong (b) (4)	09 Mar 2021 21:26:14
User entered 'LVM'	(b) (4), (b) (6)	09 Mar 2021 16:29:40

US3052380

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:29:46

US3052380

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:38:54
User entered 'I'	System	09 Mar 2021 16:29:46

US3052380

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4)	23 Mar 2021 14:00:57

US3052380

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	(b) (4), (b) (6) 24 Mar 2021 14:52:57
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'dates confirmed' (Site from System).		23 Mar 2021 14:01:11
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Mar 2021 14:00:57
User entered '19 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 14:00:57

US3052380

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:00:57

US3052380

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered 'VISIT4'	System	23 Mar 2021 14:00:57

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '15:56'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered '19 Mar 2021 15:56'	System	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '37.0' C	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Oral (Oral)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '107'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered 'bpm'	System	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '16'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered 'breaths/min'	System	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '120'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered 'mmHg'	System	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '78'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered 'mmHg'	System	30 Mar 2021 22:01:10

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02

US3052380

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02

US3052380

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:01:24

US3052380

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4)	23 Mar 2021 14:01:24

US3052380

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 14:01:50

US3052380

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:01:50

US3052380

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '16:25'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:01:50

US3052380

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered '19 Mar 2021 16:25'	System	23 Mar 2021 14:01:50

US3052380

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Mar 2021 14:02:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 14:02:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 14:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 14:01:56
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 14:01:56

US3052380

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:37:02
User entered '1'	System	23 Mar 2021 14:02:03
User entered empty.	System	23 Mar 2021 14:01:56

US3052380

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

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:23

US3052380

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

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:23

US3052380

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

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[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 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:23

US3052380

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

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 14:11:23

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[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 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:34:31
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:04:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:34:06

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:34:31
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4)	12 Apr 2021 15:32:37
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 19:04:37
User entered 'Amendment 6 or later (Amendment 6 or later)'		09 Apr 2021 19:04:33
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		08 Apr 2021 19:01:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:34:06

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:34:31
User closed query 'Per IRT, this subject received placebo for Day 29 Dosing. Please update data else clarify.' (Site from DM).	(b) (4)	12 Apr 2021 15:50:22
Query 'Per IRT, this subject received placebo for Day 29 Dosing. Please update data else clarify.' answered with 'verified' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 19:06:19
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 19:05:45
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:05:45
User opened query 'Per IRT, this subject received placebo for Day 29 Dosing. Please update data else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:40:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '1'	System	25 Jan 2021 14:11:43

US3052380

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

Form: Unblinding

Generated On: 09 Jun 2021 15:00:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'I'	System	25 Jan 2021 14:11:43

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '188' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '96' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '27.16161'	System	25 Jan 2021 14:13:42
DataPoint set to visible.	System	25 Jan 2021 14:11:43

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '188' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '96' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '27.16161'	System	25 Jan 2021 14:13:42
DataPoint set to visible.	System	25 Jan 2021 14:11:43

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User accepted default value 'Pre-Dose (PREDOSE)'		25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '12:18'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '23 Jan 2021 12:18'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '37.2' C	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '104'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'bpm'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'breaths/min'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '128'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'mmHg'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '84'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'mmHg'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '188' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '96' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:00:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '27.16161'	System	25 Jan 2021 14:13:42
DataPoint set to visible.	System	25 Jan 2021 14:11:43

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User accepted default value 'Post-Dose (POSTDOSE)'		25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '13:41'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '23 Jan 2021 13:41'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '105'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'bpm'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'breaths/min'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '120'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'mmHg'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '82'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:42

US3052380

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'mmHg'	System	25 Jan 2021 14:13:42

US3052380

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:54

US3052380

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:54

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

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 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'mRNA-1273'	System	25 Jan 2021 14:14:17
DataPoint set to visible.	System	25 Jan 2021 14:11:43

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '13:00'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '23 Jan 2021 13:00'	System	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'ONCE'	System	25 Jan 2021 14:14:17

US3052380

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

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 14:14:17

US3052380

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:48

US3052380

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:48

US3052380

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '12:54'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:14:48

US3052380

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '23 Jan 2021 12:54'	System	25 Jan 2021 14:14:48

US3052380

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:15:06

US3052380

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 23JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 10:45:27
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 23JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'Updated in PPD' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 15:13:52
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 23JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).		05 Feb 2021 09:20:45
User entered '23 Jan 2021'		25 Jan 2021 14:15:06

US3052380

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '12:59'	(b) (4), (b) (6)	25 Jan 2021 14:15:06

US3052380

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:00:44

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered '23 Jan 2021 12:59'	System	25 Jan 2021 14:15:06

US3052380

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

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:15:19

US3052380

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

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'I'	System	25 Jan 2021 14:15:19

US3052380

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:56:04

US3052380

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 10:22:28
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed call performed 2/4/2021' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 16:54:00
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:23:10
User entered '04 Feb 2021'	(b) (4), (b) (6)	05 Feb 2021 14:56:04

US3052380

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	05 Feb 2021 14:56:04

US3052380

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'lvm'	(b) (4), (b) (6)	05 Feb 2021 14:56:04

US3052380

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:56:12

US3052380

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'I'	System	05 Feb 2021 14:56:12

US3052380

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered '1'	System	05 Feb 2021 14:56:12
DataPoint set to visible.	System	05 Feb 2021 14:56:12

US3052380

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 16:29:22
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '17 Feb 2021'	(b) (4)	19 Feb 2021 16:29:22
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[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 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:29:22

US3052380

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'OLD29'	System	19 Feb 2021 16:29:22

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User accepted default value 'Pre-Dose (PREDOSE)'		19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '09:50'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered '17 Feb 2021 09:50'	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Oral (Oral)'	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '78'	(b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'bpm'	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'breaths/min'	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '112'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'mmHg'	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '80'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'mmHg'	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User accepted default value 'Post-Dose (POSTDOSE)'		19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered empty.	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered empty.	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered empty.	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered empty.	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:33:47
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered empty.	System	19 Feb 2021 16:33:47

US3052380

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:33:55

US3052380

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '17 Feb 2021'	(b) (4)	19 Feb 2021 16:33:55

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4)	19 Feb 2021 16:34:26
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

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 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'mRNA-1273'	System	19 Feb 2021 16:34:26
DataPoint set to visible.	System	05 Feb 2021 14:56:12

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered '11:02'	(b) (4)	19 Feb 2021 16:34:26
	(b) (4), (b) (6)	

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered '17 Feb 2021 11:02'	System	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'ONCE'	System	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:00:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 16:34:26

US3052380

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:34:30

US3052380

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'I'	System	19 Feb 2021 16:34:30

US3052380

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	16 Mar 2021 00:02:39
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	15 Mar 2021 15:42:30
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 15:42:30

US3052380

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:42:30

US3052380

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty; reason for change Data Entry Error	amy sheets (b) (4)	16 Mar 2021 00:02:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	15 Mar 2021 15:42:30

US3052380

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:00:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'missed'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:42:30

US3052380

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:42:37

US3052380

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:00:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:06
User entered 'I'	System	15 Mar 2021 15:42:37

US3052380

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4)	23 Mar 2021 14:02:22

US3052380

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4)	(b) (4), (b) (6)

US3052380

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[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 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:02:22

US3052380

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:00:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'OLD57'	System	23 Mar 2021 14:02:22

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '15:56'	(b) (4)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered '19 Mar 2021 15:56'	System	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '37' C	(b) (4)	(b) (4), (b) (6)

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '107'	(b) (4), (b) (6)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'bpm'	System	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '16'	(b) (4), (b) (6)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'breaths/min'	System	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '120'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'mmHg'	System	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '78'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered 'mmHg'	System	23 Mar 2021 14:03:51

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05

US3052380

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:00:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05

US3052380

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:04:14

US3052380

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:00:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4)	23 Mar 2021 14:04:14

US3052380

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4)	23 Mar 2021 14:05:03

US3052380

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:05:03

US3052380

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '16:25'	(b) (4)	23 Mar 2021 14:05:03

US3052380

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:00:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:05
User entered '19 Mar 2021 16:25'	System	23 Mar 2021 14:05:03

US3052380

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:00:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:20:07
Data hard unlocked.		04 May 2021 05:19:54
Data hard locked.		03 May 2021 07:10:45
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:08:45

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:12
User entered 'USA-US117-2021-mRNA-1273-P301000005'	System	24 Mar 2021 13:22:00
User entered 'New'	(b) (4), (b) (6)	24 Mar 2021 13:22:00

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Mar 2021 14:29:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 14:29:46
Data point term sent to Coder	System	23 Mar 2021 14:18:48
User entered 'herneated disks'	(b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	23 Mar 2021 14:22:59
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	23 Mar 2021 14:22:59
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 14:22:59
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	23 Mar 2021 14:21:15
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	23 Mar 2021 14:21:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 14:21:15
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 14:21:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 14:19:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 14:19:52
User entered '1 Sep 2020' (non-conformant).	(b) (4), (b) (6)	23 Mar 2021 14:19:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 14:18:41
User entered '1 Sep 2020' (non-conformant).	(b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
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	23 Mar 2021 14:19:52
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	23 Mar 2021 14:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 15:09:45
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:10:12
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 02:45:45
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		23 Mar 2021 14:19:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 14:19:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Mar 2021 14:18:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:27:37
User closed query 'PV Query: As it was confirmed that subject received second dose of placebo on 08 Oct 2020, please update the action taken with study drug to None. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:32:02
Query 'PV Query: As it was confirmed that subject received second dose of placebo on 08 Oct 2020, please update the action taken with study drug to None. ' answered with 'updated' (Site from Safety).		23 Apr 2021 19:51:41
Signature has been broken.		23 Apr 2021 19:51:18
User entered 'None (NONE)' reason for change: Data Entry Error		23 Apr 2021 19:51:18
User opened query 'PV Query: As it was confirmed that subject received second dose of placebo on 08 Oct 2020, please update the action taken with study drug to None. ' (Site from Safety).		23 Apr 2021 19:48:03
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User closed query 'PV Query: Please confirm if the subject received second dose of placebo on 08 Oct 2020. If yes, then kindly update the action taken to none from not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:35:31
Query 'PV Query: Please confirm if the subject received second dose of placebo on 08 Oct 2020. If yes, then kindly update the action taken to none from not applicable.' answered with 'completed' (Site from Safety).		17 Apr 2021 13:09:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		17 Apr 2021 13:08:58
User entered 'None (NONE)' reason for change: Data Entry Error		01 Apr 2021 13:22:33
User opened query 'PV Query: Please confirm if the subject received second dose of placebo on 08 Oct 2020. If yes, then kindly update the action taken to none from not applicable.' (Site from Safety).		01 Apr 2021 02:45:23
User entered 'Not Applicable (NOT APPLICABLE)'		23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for your recent response but records were not received. Please resend 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). Query 'PV Query: Thank you for your recent response but records were not received. Please resend 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 'records emailed to the email address given in the query 4/27/2021 @ 10:33 am eastern ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 13:08:16
User opened query 'PV Query: Thank you for your recent response but records were not received. Please resend 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).		27 Apr 2021 14:37:15
User closed query 'PV Query: Please provide the details of any signs and symptoms experienced by the subject?' (Site from Safety).		23 Apr 2021 19:48:13
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		20 Apr 2021 15:09:56
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).		20 Apr 2021 15:09:53
		20 Apr 2021 15:09:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

1960 of 2185

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'tests and results contain within the records' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:10:34
Query 'PV Query: Please provide the details of any signs and symptoms experienced by the subject?' answered with 'chronic numbness and tingling histor of lumbar discomfort with left leg radicular symptoms' (Site from Safety).		19 Apr 2021 17:29:46
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 'Testing not done' (Site from Safety).		19 Apr 2021 17:27:58
User entered 'ON 18 FEB 2021 PATIENT HAD THREE HERNIATED DISKS REMOVED FROM THE NECK AT PINEHURST SURGICAL (b) (6) (b) (6) . WAS INPATIENT OVERNIGHT LEFT 19 FEB 2021' reason for change: Data Entry Error		17 Apr 2021 13:29:41
User opened query 'PV Query: Please provide the details of any signs and symptoms experienced by th subject?' (Site from Safety).		01 Apr 2021 02:45:52
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		01 Apr 2021 02:45:38
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).		01 Apr 2021 02:45:31
User entered 'ON 18 FEB 2021 PATIENT HAD THREE HERNIATED DISKS REMOVED From THE NECK AT PINEHURST SURGICAL (b) (6) (b) (6) . WAS INNPATIENT OVERNIGHT LEFT 19 FEB 2021' reason for change: Data Entry Error		23 Mar 2021 14:19:52

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'on 18 feb 2021 patient had three herniated disks removed for the neck at pinehurst surgical (b) (6) . was innpatient overnight left 19 feb 2021'	(b) (4), (b) (6)	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 14:18:41

US3052380

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 14:18:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:00:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:10:48

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;TELMISARTAN, PRODUCTSYNONYM: TELMISARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:31:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:31:36
Data point term sent to Coder	System	20 Oct 2020 19:29:17
User entered 'telmisartan hydrochlorothiazide'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'htn'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'mg (mg)'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered empty.	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:29:15
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:29:15

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Oct 2020 19:33:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:33:44
Data point term sent to Coder	System	20 Oct 2020 19:32:20
User entered 'Atorvastatin'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'hld'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered '80'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'mg (mg)'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered '0'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:31:38
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:31:38

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 18:25:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 18:25:19
Data point term sent to Coder Coding entries removed.	System	29 Oct 2020 18:58:22
	Stacey Saldua (b) (4)	29 Oct 2020 18:58:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:34:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:34:37
Data point term sent to Coder User entered 'Divalproex sodium'	System	20 Oct 2020 19:34:22
	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'bipolar disorder' reason for change:	Stacey Saldua (b) (4)	29 Oct 2020 18:58:06
Data Entry Error	(b) (4)	
User entered 'mood disorder'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
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). 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). User entered '500' reason for change: Data Entry Error User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). User entered '50'	(b) (4), (b) (6)	08 Feb 2021 13:38:03 05 Feb 2021 15:34:37 05 Feb 2021 15:34:27 11 Jan 2021 02:26:39
	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'mg (mg)'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered '0'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:34:17
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:34:17

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Oct 2020 05:05:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:05:30
Data point term sent to Coder	System	20 Oct 2020 19:37:32
User entered 'magnesium'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per DM CLR: This medication was as VITAMIN. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 13:38:21
Query 'Per DM CLR: This medication was as VITAMIN. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' answered with 'updated' (Site from DM).		05 Feb 2021 15:35:01
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Feb 2021 15:34:50
User opened query 'Per DM CLR: This medication was as VITAMIN. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' (Site from DM).		11 Jan 2021 02:26:52
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'vitamin'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered '450'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'mg (mg)'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:37:19
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:37:19

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:40:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:40:42
Data point term sent to Coder	System	20 Oct 2020 19:39:37
User entered 'aspirin'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per DM CLR: This medication was given for HEART HEALTH. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' (Site from DM). Query 'Per DM CLR: This medication was given for HEART HEALTH. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error User opened query 'Per DM CLR: This medication was given for HEART HEALTH. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable. ' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:38:34 05 Feb 2021 15:35:20 05 Feb 2021 15:35:12 11 Jan 2021 02:27:03
	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'heart health'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered '325'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'mg (mg)'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:38:41
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:38:41

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:28:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:28:45
Data point term sent to Coder	System	05 Feb 2021 15:49:34
Coding entries removed.	(b) (4), (b) (6)	05 Feb 2021 15:48:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:42:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:42:49
Data point term sent to Coder	System	20 Oct 2020 19:41:41
User entered 'percocet'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User closed query 'Per DM CLR: Please note that this condition 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).	(b) (4), (b) (6)	08 Feb 2021 13:39:35
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).		08 Feb 2021 13:39:33
Query 'Per DM CLR: Please note that this condition 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.' answered with 'MH updated' (Site from DM).		05 Feb 2021 15:49:18
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'updated' (Site from DM).		05 Feb 2021 15:49:10
User entered 'bilateral knee PAIN/neck back, shoulder pain' reason for change: Data Entry Error		05 Feb 2021 15:48:50
User opened query 'Per DM CLR: Please note that this condition 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).		11 Jan 2021 02:27:50
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).		11 Jan 2021 02:27:42
User entered 'pain'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered '10/325'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'mg (mg)'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered '0'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4) (b) (4)	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:41:21
	(b) (4)	

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:41:21

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HCV INFECTIONS, PRODUCT: LEDIPASVIR;SOFOSBUVIR, PRODUCTSYNONYM: HARVONI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:48:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:48:40
Data point term sent to Coder User entered 'Harvoni'	System Stacey Saldua (b) (4)	20 Oct 2020 19:48:02 20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'hepatitis c'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'unknown'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Other (OTHER)'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'unknown'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'unknown (UNKNOWN)'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'Other (OTHER)'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'unknown'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered empty.	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'I'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'UN UNK 2016'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
User entered 'No (N)'	Stacey Saldua (b) (4)	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User entered empty.	System	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User entered empty.	System	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:00:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:10:55
User entered empty.	System	20 Oct 2020 19:47:26

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:00:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:45
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 14:23:19
User entered 'Yes (Y)' reason for change: Data Entry Error		23 Mar 2021 14:23:19
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 17:27:04
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	20 Oct 2020 19:50:19
	(b) (4)	
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	20 Oct 2020 19:49:51
	(b) (4)	

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:26:16

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'discectomy'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:26:16

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:26:16

US3052380

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:00:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:26:16

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'USA-US117-2021-MRNA-1273-P301000005'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yaa'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Oppong'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '1565 Purdue Drive'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Fayetteville'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'NC'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '28314'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:27:21
User entered 'US'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 15:32:34
User entered '3'	System	19 Apr 2021 14:36:03
User entered '2'	System	02 Apr 2021 14:27:31
User entered '1'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'USA-US117-2021-MRNA-1273-P301000005'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yaa'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Oppong'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '1565 Purdue Drive'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Fayetteville'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'NC'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '28314'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:27:21
User entered 'US'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 15:32:34
User entered '3'	System	19 Apr 2021 14:36:03
User entered '2'	System	02 Apr 2021 14:27:31
User entered '1'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:00:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '24/Mar/2021 08:22'	(b) (4) System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:00:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:27:21
User entered 'I'		24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'USA-US117-2021-MRNA-1273-P301000005'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yaa'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Oppong'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '1565 Purdue Drive'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Fayetteville'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'NC'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '28314'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:27:21
User entered 'US'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 15:32:34
User entered '3'	System	19 Apr 2021 14:36:03
User entered '2'	System	02 Apr 2021 14:27:31
User entered '1'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:00:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered '02/Apr/2021 09:27'	(b) (4) System	02 Apr 2021 14:27:31

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:00:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:46
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 14:27:31

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'USA-US117-2021-MRNA-1273-P301000005'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yaa'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Oppong'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '1565 Purdue Drive'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Fayetteville'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'NC'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '28314'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:27:21
User entered 'US'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 15:32:34
User entered '3'	System	19 Apr 2021 14:36:03
User entered '2'	System	02 Apr 2021 14:27:31
User entered '1'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:00:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered '19/Apr/2021 10:36'	(b) (4) System	19 Apr 2021 14:36:03

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:00:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:13:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:36:03

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'USA-US117-2021-MRNA-1273-P301000005'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yes (Y)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'No (N)'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Yaa'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Oppong'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '1565 Purdue Drive'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'Fayetteville'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered 'NC'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:22:48
User entered '28314'	System	24 Mar 2021 13:22:00

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:27:21
User entered 'US'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:00:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Apr 2021 15:32:34
User entered '3'	System	19 Apr 2021 14:36:03
User entered '2'	System	02 Apr 2021 14:27:31
User entered '1'	System	24 Mar 2021 13:22:57

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:00:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:37:06
User entered '26/Apr/2021 11:32'	(b) (4) System	26 Apr 2021 15:32:34

US3052380

Folder: SAE USA-US117-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:00:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:37:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:32:34