

US3052295 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:57:25

All time stamps listed in this document are displayed in GMT

US3052295

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 16:47:56

Generated On: 09 Jun 2021 14:57:25

[Participant ID](#)

US3052295

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Date of Birth (MMM yyyy)	(b) (6) 1982
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	MITRAL VALVE PROLAPSE
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3052295

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	CONIZATION OF THE CERVIX
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	BLOOD TRANSFUSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:50
Height (xxx.x)	66 in
Weight (xxx.x)	197 lb
BMI (xxx.x)	31.86312 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Mar 2021 16:48:15

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Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2018

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 16:48:15

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 107311

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:50
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)	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)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:03
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

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

Treatment Date and Time (derived) 24 AUG 2020 10:28

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

10:18 (24 HR)

Collection date and time (derived)

24 AUG 2020 10:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:20	24 AUG 2020 10:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 11:13

PC Open Date & Time

24 AUG 2020 10:48

PC Close Date & Time

24 AUG 2020 13:18

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	25 AUG 2020 09:52
PC Open Date & Time	24 AUG 2020 14:13
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 AUG 2020 09:37

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 09:53

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 16:11

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 13:09

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 09:18

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 11:14

PC Open Date & Time

24 AUG 2020 10:48

PC Close Date & Time

24 AUG 2020 13:18

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

25 AUG 2020 09:52

PC Open Date & Time

24 AUG 2020 14:13

PC Close Date & Time

25 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 09:37

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 09:53

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 16:11

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 13:10

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 09:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 11:15
PC Open Date & Time	24 AUG 2020 10:48
PC Close Date & Time	24 AUG 2020 13:18

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 09:53
PC Open Date & Time	24 AUG 2020 14:13
PC Close Date & Time	25 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 09:38
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 09:54
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

Yes ☐

PC Time stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

56 of 2240

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 16:11
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2240

EAB) (1725)

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 13:10
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

60 of 2240

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 09:19
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:20
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

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)	23 SEP 2020
Time of assessment (00:00-23:59)	14:32 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 14:32
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3052295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 SEP 2020

What was the treatment time? (00:00-23:59) 14:02 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 14:02

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

US3052295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

23 SEP 2020 13:30

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:32	23 SEP 2020 13:32
Nasopharyngeal Swab 2	No		

US3052295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 14:30

PC Open Date & Time

23 SEP 2020 14:22

PC Close Date & Time

23 SEP 2020 16:52

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 23 SEP 2020 17:47

PC Close Date & Time 24 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 SEP 2020 13:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

26 SEP 2020 13:30

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

29 SEP 2020 07:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 7

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 14:31

PC Open Date & Time

23 SEP 2020 14:22

PC Close Date & Time

23 SEP 2020 16:52

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 17:47

PC Close Date & Time

24 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 13:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 07:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 14:31
PC Open Date & Time	23 SEP 2020 14:22
PC Close Date & Time	23 SEP 2020 16:52

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 17:47

PC Close Date & Time

24 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☒

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☒

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 13:31
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☒

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☒

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

No ☐

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EAB) (1725)

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 07:15
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

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

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052295

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

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Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity ☐
not requiring medical attention

Prevents daily activity and ☐
requires medical attention

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

PC Time stamp

US3052295

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3052295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

VM LEFT

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 NOV 2020
Time of assessment (00:00-23:59)	08:43 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 08:43
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3052295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 NOV 2020

Collection time (00:00-23:59)

09:12 (24 HR)

Collection date and time (derived)

30 NOV 2020 09:12

US3052295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 NOV 2020 13:40:13
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	02 DEC 2020 13:28:52
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:35:43

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:11:09

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

31 DEC 2020 16:44:15

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 06:10:16

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 17:59:31
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 FEB 2021 16:26:46
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 12:00:42

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 16:49:48

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 19:55:56

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 17:15:13

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 11:59:30

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 13:28:45

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 09:53:33

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2021 00:01
Patient Cloud Close Date & Time	11 JUL 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 362

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 404

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 453

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 488

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 509

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 544

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 565

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 649

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Patient Cloud Open Date & Time	12 OCT 2022 00:01
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

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

Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3052295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:57:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 MAR 2021 15:41:18

US3052295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:47:57

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:48:15

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:11 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 10:11
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052295

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3052295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	04 MAR 2021
Collection time (<i>00:00-23:59</i>)	12:11 (24 HR)
Collection date and time (derived)	04 MAR 2021 12:11

US3052295

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 19:53:53

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 19:53:53

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052295

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:57:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3052295

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:28:16

Generated On: 09 Jun 2021 14:57:25

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

Visit date (dd MMM yyyy)	04 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	UNBLND_DECIDE
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US3052295

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 MAR 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>)	04 MAR 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

US3052295

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Height	168 cm
Weight	90 kg
BMI (xxx.x)	31.88776

US3052295

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Height	168 cm
Weight	90 kg
BMI (xxx.x)	31.88776
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)	04 MAR 2021
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 10:11
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3052295

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Height	168 cm
Weight	90 kg
BMI (xxx.x)	31.88776
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)	04 MAR 2021
Time of assessment (00:00-23:59)	12:47 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 12:47
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	175 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3052295

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:51:50

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3052295

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 04 MAR 2021

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 12:13

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

US3052295

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:51:50

Generated On: 09 Jun 2021 14:57:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	12:11 (24 HR)
Collection date and time (derived)	04 MAR 2021 12:11

US3052295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 19:51:50

Generated On: 09 Jun 2021 14:57:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00 - 23:59)	12:05
Collection Date and Time (derived)	04 MAR 2021 12:05

US3052295

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:50

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 08:55
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

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)	30 MAR 2021
Time of assessment (00:00-23:59)	10:29 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:29
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3052295

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3052295

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 30 MAR 2021

What was the treatment time? (00:00-23:59) 09:56 (24 HR)

Treatment Date and Time (derived) 30 MAR 2021 09:56

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

US3052295

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 16:31:26

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052295

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052295

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052295

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 16:47:56

Generated On: 09 Jun 2021 14:57:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 19:51:49

Generated On: 09 Jun 2021 14:57:25

AEID	USA-US117-2020-MRNA-1273-P30 1000002
Adverse event	SYNCOPE
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)	24 SEP 2020
Start time (00:00-23:59)	14:08 (24 HR)
AE start date and time (derived)	24 SEP 2020 14:08
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	10:18 (24 HR)
AE End Date and Time (derived)	25 SEP 2020 10:18
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)	24 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	26 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 19:51:49

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 19:51:49

Generated On: 09 Jun 2021 14:57:25

SEIZURE LIKE ACTIVITY WITH
SOME TRANSIENT
NEUROLOGIC SYMPTOMS.
WAS ADMITTED FOR
THOROUGH WORKUP WITH
NORMAL (NEGATIVE) MRI,
EEG, ECHO. NEUROLOGIST
DDX: CONVULSIVE SYNCOPE,
SEIZURE, PSEUDOSEIZURE.
DISCHARGED HOME AFTER A
NEGATIVE WORKUP. PATIENT
AT BASELINE WITH NO
RESIDUAL ON DISCHARGE.

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

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 19:51:49

Generated On: 09 Jun 2021 14:57:25

AEID

Adverse event

CONSTIPATION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 19:51:49

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 19:51:50

Generated On: 09 Jun 2021 14:57:25

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

Yes ☒

No ☐

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

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication DEEP VEIN THROMBOSIS
PREVENTION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

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

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

Name of Medication SENOKOT

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:59:44

Generated On: 09 Jun 2021 14:57:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 16:47:56

Generated On: 09 Jun 2021 14:57:25

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Mar 2021 16:47:56

Generated On: 09 Jun 2021 14:57:25

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 SEP 2020	2D ECHOCARDIOGRAM	Adverse Event	
24 SEP 2020	CT SCAN	Adverse Event	
24 SEP 2020	MRI	Adverse Event	
24 SEP 2020	EEG	Adverse Event	
24 SEP 2020	TRANSTHORACIC ECHO	Adverse Event	
24 SEP 2020	ULTRASOUND CAROTID DOPPLER BILATERAL	Adverse Event	

US3052295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:25

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3052295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:25

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/OCT/2020 12:37
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

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/NOV/2020 15:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:46
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

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/NOV/2020 21:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Apr 2021 02:32:39

Generated On: 09 Jun 2021 14:57:25

SAEID	USA-US117-2020-MRNA-1273-P301000002
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	JUDITH
Investigator's Last Name	BORGER
Site Address: Street	1565 PURDUE DRIVE, SUITE 101
Site Address: City	FAYETTEVILLE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/FEB/2021 09:59
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

US3052295 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052295

Form: Participant Creation

Generated On: 09 Jun 2021 14:57:25

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:49:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'US3052295'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:09:49

US3052295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:10:11

US3052295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:28
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:09:50

US3052295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 15:10:11

US3052295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'SCRN'	System	24 Aug 2020 15:10:11

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:39
User entered (b) (6) 1982'	(b) (4), (b) (6)	
	RWS_ENDPOINT	24 Aug 2020 14:09:51
	ENDPOINT (b) (4)	

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:39
Query 'Per CDM please complete the form.' canceled (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:35:48
User entered '38'		02 Sep 2020 18:08:23
User opened query 'Per CDM please complete the form.' (Site from DM).		01 Sep 2020 09:05:57

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'YEARS'	System	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '38'	System	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:39
User entered 'Female (F)'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered 'l'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:43:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 18:08:23

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:05:03
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:18:07
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	29 Sep 2020 15:18:07
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	24 Aug 2020 15:10:55
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Aug 2020'	System	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2020'	System	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:03
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:03
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:03
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:03
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 15:10:32

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:05:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:09:50

US3052295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'I'	System	24 Aug 2020 15:10:38

US3052295

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:05:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:10:38

US3052295

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:57:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:10
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	29 Oct 2020 13:20:29

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:35
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve prolapse, LLT: Mitral valve prolapse - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:46:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:46:54
Data point term sent to Coder	System	29 Oct 2020 13:23:00
User entered 'mitral valve prolapse'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'UN UNK 1994'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	18 Nov 2020 18:06:35
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 1994'	System	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '1994'	System	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:22:14

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:35
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:46:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:46:55
Data point term sent to Coder	System	29 Oct 2020 13:23:00
User entered 'Anxiety'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'UN UNK 2010'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2010'	System	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2010'	System	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:22:58

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User closed query 'Per CDM CLR: Response noted; please update the AE term to reflect the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 08:32:49
Query 'Per CDM CLR: Response noted; please update the AE term to reflect the response. Thank you.' answered with 'this is prior to ICF no AE is applicable to this medical history event.' (Site from DM).	amy sheets (b) (4) (b) (4)	24 Mar 2021 17:58:23
User opened query 'Per CDM CLR: Response noted; please update the AE term to reflect the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 07:00:28
User closed query 'Per DM CLR: Please update the condition to confirm if the sample of the abnormal tissue was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		03 Feb 2021 06:58:21
Query 'Per DM CLR: Please update the condition to confirm if the sample of the abnormal tissue was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'pre-cancerous cells -benign' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:24:33
User opened query 'Per DM CLR: Please update the condition to confirm if the sample of the abnormal tissue was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 12:06:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Cervix therapeutic procedures, PT: Cervical conisation, LLT: Cervical conization - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:45:55

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. DataPoint Verified.	Coder Import (b) (4)	23 Nov 2020 11:45:55
	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:06:35
Data point term sent to Coder	System	11 Nov 2020 15:59:31
User closed query 'CDM-Coding,For coding purposes, Please expand/spell out the reported abbreviation CKC and provide the full text. ' (Site from System).	System	11 Nov 2020 15:59:05
Query 'CDM-Coding,For coding purposes, Please expand/spell out the reported abbreviation CKC and provide the full text. ' answered with 'updated' (Site from System).	Avia McClain-Stocker	11 Nov 2020 15:59:05
	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 15:58:29
User entered 'Conization of the cervix' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:58:18
	(b) (4)	
User opened query 'CDM-Coding,For coding purposes, Please expand/spell out the reported abbreviation CKC and provide the full text. ' (Site from System).	Coder Import (b) (4)	06 Nov 2020 07:46:31
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 13:25:08
User entered 'CKC'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:06
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'UN UNK 2003'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	18 Nov 2020 18:06:35
User entered 'No (N)'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'UN UNK 2003'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2003'	System	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2003'	System	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2003'	System	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2003'	System	29 Oct 2020 13:25:06

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:52:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:52:16
Data point term sent to Coder	System	02 Nov 2020 15:44:46
User closed query 'For coding purposes, please clarify/provide more information for term WISDOM TEETH. Is this Impacted wisdom tooth, Wisdom teeth removal or something else. ' (Site from System).	System	02 Nov 2020 15:44:24
Query 'For coding purposes, please clarify/provide more information for term WISDOM TEETH. Is this Impacted wisdom tooth, Wisdom teeth removal or something else. ' answered with 'updated per source' (Site from System).	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:44:24
User entered 'WISDOM TEETH removal' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:43:49
User opened query 'For coding purposes, please clarify/provide more information for term WISDOM TEETH. Is this Impacted wisdom tooth, Wisdom teeth removal or something else. ' (Site from System).	Coder Import (b) (4) (b) (4)	01 Nov 2020 14:20:46
Data point term sent to Coder	System	29 Oct 2020 13:26:12
User entered 'Wisdom Teeth'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	18 Nov 2020 18:06:35
User entered 'l'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'No (N)'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'l'	Stacey Saldua (b) (4)	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	29 Oct 2020 13:25:43

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:31:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'leading condition is in source' (Site from DM).		01 Apr 2021 13:16:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		08 Jan 2021 12:06:47
DataPoint Verified.		18 Nov 2020 18:06:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Haematological and lymphoid tissue therapeutic procedures, HLT: Blood and blood product treatment, PT: Transfusion, LLT: Blood transfusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:47:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:47:25
Data point term sent to Coder	System	29 Oct 2020 13:27:13
User entered 'Blood Transfusion'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'UN UNK 2018'	Stacey Saldua (b) (4)	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'No (N)'	Stacey Saldua (b) (4)	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	18 Nov 2020 18:06:35
User entered 'UN UNK 2018'	Stacey Saldua (b) (4)	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2018'	System	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2018'	System	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2018'	System	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2018'	System	29 Oct 2020 13:26:53

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:51:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:51:58
Data point term sent to Coder	System	02 Nov 2020 15:48:50
Coding entries removed.	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:48:32
User entered 'bilateral TUBAL LIGATION' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:48:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:48:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:48:23
Data point term sent to Coder	System	29 Oct 2020 13:28:14
User entered 'Tubal Ligation'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'UN UNK 2018'	Stacey Saldua (b) (4)	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered 'No (N)'	Stacey Saldua (b) (4)	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	18 Nov 2020 18:06:35
User entered 'UN UNK 2018'	Stacey Saldua (b) (4)	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:06:35
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2018'	System	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2018'	System	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2018'	System	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2018'	System	29 Oct 2020 13:27:39

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:59:59
DataPoint Un-verified.		07 Apr 2021 19:58:13
DataPoint Verified.		07 Apr 2021 19:58:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:59:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:59:20
Data point term sent to Coder	System	28 Jan 2021 18:58:54
User entered 'seasonal allergies'	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
DataPoint Verified.		16 Apr 2021 15:22:10
User closed query 'Please update MH Log. ConMed lot starts indication started on Un Unk 2000. Please review and reconcile.' (Site from CRA).		16 Apr 2021 15:21:41
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Please update MH Log. ConMed lot starts indication started on Un Unk 2000. Please review and reconcile.' answered with 'done' (Site from CRA).	(b) (4)	
User entered 'UN UNK 2000' reason for change:	(b) (4), (b) (6)	09 Apr 2021 16:36:01
Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:35:55
User opened query 'Please update MH Log. ConMed lot starts indication started on Un Unk 2000. Please review and reconcile.' (Site from CRA).		07 Apr 2021 19:58:59
DataPoint Un-verified.		07 Apr 2021 19:58:15
DataPoint Verified.		07 Apr 2021 19:58:11
User entered 'un UNK 2018'	Stacey Saldua (b) (4)	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered '0'	Stacey Saldua (b) (4)	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered empty.	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered '0'	Stacey Saldua (b) (4)	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2000'	System	09 Apr 2021 16:35:55
User entered 'Jan 2018'	System	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2000'	System	09 Apr 2021 16:35:55
User entered '2018'	System	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	28 Jan 2021 18:58:10

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:59:55
DataPoint Un-verified.		07 Apr 2021 19:59:11
DataPoint Verified.		07 Apr 2021 19:58:11
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 19:23:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 19:23:22
Data point term sent to Coder	System	28 Jan 2021 19:22:16
User entered 'high cholesterol'	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User closed query 'Please update on MH Log.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:22:07
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Please update on MH Log.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:36:52
User opened query 'Please update on MH Log.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:59:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered 'un UNK 2020'	Stacey Saldua (b) (4)	28 Jan 2021 19:21:48
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered '0'	Stacey Saldua (b) (4)	28 Jan 2021 19:21:48

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered empty.	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:58:11
User entered '0'	Stacey Saldua (b) (4)	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'Jan 2020'	System	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '2020'	System	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered empty.	System	28 Jan 2021 19:21:48

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	02 Nov 2020 15:46:52
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Nov 2020 15:46:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:52
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	02 Nov 2020 15:46:40
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Nov 2020 15:46:40
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	29 Sep 2020 15:16:38
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	29 Sep 2020 15:16:15
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered '24 Aug 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:16:38
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).		29 Sep 2020 15:16:38
User entered empty; reason for change Data Entry Error	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:38
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:16:15
User entered '24 Aug 2020'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered '09:50' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 09:50'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered '66' in reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4)	29 Sep 2020 15:16:15
DataPoint set to visible.	(b) (4) System	24 Aug 2020 15:10:38

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered '197' lb reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4)	29 Sep 2020 15:16:15
DataPoint set to visible.	(b) (4) System	24 Aug 2020 15:10:38

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '31.86312'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15
DataPoint set to visible.	System	24 Aug 2020 15:10:38

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'kg/m2'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15
DataPoint set to visible.	System	24 Aug 2020 15:10:38

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:47:20
User entered '98.6' F reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:47:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 15:47:20
User entered '78' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 15:46:40
User entered empty.	(b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'bpm'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:47:20
User entered '16' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'breaths/min'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:47:20
User entered '112' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:46:40
User entered empty.	Nicole Davis (b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'mmHg'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 15:47:20
User entered '81' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 15:46:40
User entered empty.	(b) (4)	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered 'mmHg'	System	02 Nov 2020 15:46:40
User entered empty.	System	29 Sep 2020 15:16:15

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:08:17
User entered 'Yes (Y)'	Nicole Davis (b) (4)	29 Sep 2020 15:17:29
	(b) (4)	

US3052295

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:17
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:18:07
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	29 Sep 2020 15:18:07
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:17:29
User entered '24 Aug 2020'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:17:29

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered '24 Aug 2020'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).		03 Nov 2020 15:53:09
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'updated per source' (Site from DM).	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:48:49
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 11:18:12
User entered 'Surgically sterile (SURGICALLY STERILE)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered 'UN UNK 2018'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered '0'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:25

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:31
User entered '0'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:14:11

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered '0'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered '0'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered '0'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered '0'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:09:08
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 18:09:08
	(b) (4)	29 Sep 2020 15:12:57
	Nicole Davis (b) (4)	29 Sep 2020 15:12:57
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:08
User entered empty.	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:12:57

US3052295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:16
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	20 Oct 2020 18:42:07
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	29 Sep 2020 15:18:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 15:10:55

US3052295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:16
User entered '24 Aug 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	20 Oct 2020 18:42:07
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:18:07
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	29 Sep 2020 15:18:07
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	29 Sep 2020 15:18:07
User entered empty; reason for change Data Entry Error	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:18:07
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	24 Aug 2020 15:11:28
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	24 Aug 2020 15:10:55
User entered '24 Jul 2020'	(b) (4), (b) (6)	24 Aug 2020 15:10:55

US3052295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[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 14:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Verified.	(b) (4)	18 Nov 2020 18:09:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 15:10:55

US3052295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'VISIT1'	System	24 Aug 2020 15:10:55

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Sep 2020 15:18:07
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	29 Sep 2020 15:18:07
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 15:10:55
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:09:58

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '107311'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:09:58

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:09:58

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:42:07
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:43:38
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:42:56
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:01:58

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	(b) (4) System	20 Oct 2020 17:43:24
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:43:24
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	20 Oct 2020 17:42:56
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:42:56

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:42:56

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:42:56

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:42:56

US3052295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:25

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:07:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker	20 Oct 2020 17:42:56
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:39:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:26:29

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered missing code ND - Not Done.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered missing code ND - Not Done.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered missing code ND - Not Done.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered missing code ND - Not Done.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Pre-Dose (PREDOSE)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '24 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '09:50'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '24 Aug 2020 09:50'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '98.6' F	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '78'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'bpm'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '16'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'breaths/min'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '112'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '87'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered missing code ND - Not Done.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered missing code ND - Not Done.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Post-Dose (POSTDOSE)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '24 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '11:03'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '24 Aug 2020 11:03'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '98.2' F	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '74'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'bpm'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '20'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'breaths/min'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '122'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '85'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	20 Oct 2020 17:49:43

US3052295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:31
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:50:06

US3052295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:31
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '24 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:50:06

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Sep 2020 15:18:07
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	29 Sep 2020 15:18:07
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 15:11:28
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '10:28'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '24 Aug 2020 10:28'	System	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:08:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.		07 Apr 2021 20:08:39
User entered 'ONCE'	System	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 15:11:28

US3052295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:09:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:54:13

US3052295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:09:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '24 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:54:13

US3052295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:09:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '10:18'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:54:13

US3052295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '24 Aug 2020 10:18'	System	20 Oct 2020 17:54:13

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:05:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '24 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:05:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:05:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '10:20'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '24 Aug 2020 10:20'	System	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:05:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 15:24:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 15:24:41
User entered 'No (N)' reason for change: Data Entry Error	Nicole Davis (b) (4)	29 Sep 2020 15:24:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 15:23:41
User entered empty.	System	29 Sep 2020 15:23:41
	Nicole Davis (b) (4)	29 Sep 2020 15:23:41
	(b) (4)	

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:05:55
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	Nicole Davis (b) (4)	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered empty.	System	29 Sep 2020 15:23:41

US3052295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:05:59
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 18:09:27
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:09:21
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	23 Sep 2020 18:26:20

US3052295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	23 Sep 2020 18:26:20

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:13:24', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '08f395ae-2581-4073-b0af-ac7ac51ce853'	System	24 Aug 2020 15:13:41
User entered 'Yes (Y)'	System	24 Aug 2020 15:13:41

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:13:29', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '08f395ae-2581-4073-b0af-ac7ac51ce853' User entered '98.2'	System	24 Aug 2020 15:13:41
	System	24 Aug 2020 15:13:41

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:13:33', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '08f395ae-2581-4073-b0af-ac7ac51ce853'	System	24 Aug 2020 15:13:41
User entered 'No (N)'	System	24 Aug 2020 15:13:41

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:13:40', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '08f395ae-2581-4073-b0af-ac7ac51ce853'	System	24 Aug 2020 15:13:41
User entered '24 Aug 2020 11:13'	System	24 Aug 2020 15:13:41

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 10:48'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 13:18'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:22', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '296f15a7-23e6-4217-80fb-183b267aa59c' User entered 'Yes (Y)'	System	25 Aug 2020 13:52:39
	System	25 Aug 2020 13:52:39

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:26', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '296f15a7-23e6-4217-80fb-183b267aa59c' User entered '97.6'	System	25 Aug 2020 13:52:39
	System	25 Aug 2020 13:52:39

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:30', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '296f15a7-23e6-4217-80fb-183b267aa59c' User entered 'No (N)'	System	25 Aug 2020 13:52:39
	System	25 Aug 2020 13:52:39

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:35', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '296f15a7-23e6-4217-80fb-183b267aa59c' User entered '25 Aug 2020 09:52'	System	25 Aug 2020 13:52:39
	System	25 Aug 2020 13:52:39

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 2'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:13', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '484f732b-a187-4cea-bb39-f8ee36d49d41' User entered 'Yes (Y)'	System	26 Aug 2020 13:37:27
	System	26 Aug 2020 13:37:27

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:17', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '484f732b-a187-4cea-bb39-f8ee36d49d41' User entered '97.9'	System	26 Aug 2020 13:37:27
	System	26 Aug 2020 13:37:27

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:21', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '484f732b-a187-4cea-bb39-f8ee36d49d41'	System	26 Aug 2020 13:37:27
User entered 'No (N)'	System	26 Aug 2020 13:37:27

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:24', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '484f732b-a187-4cea-bb39-f8ee36d49d41' User entered '26 Aug 2020 09:37'	System	26 Aug 2020 13:37:27
	System	26 Aug 2020 13:37:27

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 3'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:52:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '756c2e73-f3e3-4704-b6ca-76db54589fbb' User entered 'Yes (Y)'	System	27 Aug 2020 13:53:31
	System	27 Aug 2020 13:53:31

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '756c2e73-f3e3-4704-b6ca-76db54589fbb' User entered '95.5'	System	27 Aug 2020 13:53:31
	System	27 Aug 2020 13:53:31

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:24', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '756c2e73-f3e3-4704-b6ca-76db54589fbb'	System	27 Aug 2020 13:53:31
User entered 'No (N)'	System	27 Aug 2020 13:53:31

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:28', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '756c2e73-f3e3-4704-b6ca-76db54589fbb' User entered '27 Aug 2020 09:53'	System	27 Aug 2020 13:53:31
	System	27 Aug 2020 13:53:31

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 4'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 5'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:04:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ef36c5de-68c2-4336-b228-72c81a16a1e4'	System	28 Aug 2020 20:11:21
User entered 'Yes (Y)'	System	28 Aug 2020 20:11:21

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:13', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ef36c5de-68c2-4336-b228-72c81a16a1e4' User entered '95.8'	System	28 Aug 2020 20:11:21
	System	28 Aug 2020 20:11:21

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:15', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ef36c5de-68c2-4336-b228-72c81a16a1e4'	System	28 Aug 2020 20:11:21
User entered 'No (N)'	System	28 Aug 2020 20:11:21

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:20', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ef36c5de-68c2-4336-b228-72c81a16a1e4' User entered '28 Aug 2020 16:11'	System	28 Aug 2020 20:11:21
	System	28 Aug 2020 20:11:21

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 6'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:09:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '385c9bf7-cb6b-46fd-85e4-f86f88f7bd2d' User entered 'Yes (Y)'	System	29 Aug 2020 17:09:23
	System	29 Aug 2020 17:09:23

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:09:14', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '385c9bf7-cb6b-46fd-85e4-f86f88f7bd2d' User entered '96.8'	System	29 Aug 2020 17:09:23
	System	29 Aug 2020 17:09:23

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:09:16', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '385c9bf7-cb6b-46fd-85e4-f86f88f7bd2d' User entered 'No (N)'	System	29 Aug 2020 17:09:23
	System	29 Aug 2020 17:09:23

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:09:19', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '385c9bf7-cb6b-46fd-85e4-f86f88f7bd2d' User entered '29 Aug 2020 13:09'	System	29 Aug 2020 17:09:23
	System	29 Aug 2020 17:09:23

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 7'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:18:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '47a453c4-bc1d-4eaa-84b5-678ade8bf1d3'	System	31 Aug 2020 13:18:56
User entered 'Yes (Y)'	System	31 Aug 2020 13:18:56

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:18:47', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '47a453c4-bc1d-4eaa-84b5-678ade8bf1d3' User entered '97.0'	System	31 Aug 2020 13:18:56
	System	31 Aug 2020 13:18:56

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:18:50', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '47a453c4-bc1d-4eaa-84b5-678ade8bf1d3'	System	31 Aug 2020 13:18:56
User entered 'No (N)'	System	31 Aug 2020 13:18:56

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:18:53', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '47a453c4-bc1d-4eaa-84b5-678ade8bf1d3'	System	31 Aug 2020 13:18:56
User entered '31 Aug 2020 09:18'	System	31 Aug 2020 13:18:56

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:13:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'b1ec42a1-18e9-4cd3-8f35-1134642196e2'	System	24 Aug 2020 15:14:17
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 15:14:17

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'b1ec42a1-18e9-4cd3-8f35-1134642196e2'	System	24 Aug 2020 15:14:17
User entered 'No (N)'	System	24 Aug 2020 15:14:17

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:05', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'b1ec42a1-18e9-4cd3-8f35-1134642196e2'	System	24 Aug 2020 15:14:17
User entered 'No (N)'	System	24 Aug 2020 15:14:17

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:11', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'b1ec42a1-18e9-4cd3-8f35-1134642196e2'	System	24 Aug 2020 15:14:17
User entered 'None (1)'	System	24 Aug 2020 15:14:17

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:15', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'b1ec42a1-18e9-4cd3-8f35-1134642196e2'	System	24 Aug 2020 15:14:17
User entered '24 Aug 2020 11:14'	System	24 Aug 2020 15:14:17

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 10:48'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 13:18'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:40', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dc15dd09-950e-4f07-b209-1a8e222017da'	System	25 Aug 2020 13:52:57
User entered 'None (1)'	System	25 Aug 2020 13:52:57

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dc15dd09-950e-4f07-b209-1a8e222017da' User entered 'No (N)'	System	25 Aug 2020 13:52:57
	System	25 Aug 2020 13:52:57

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:46', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dc15dd09-950e-4f07-b209-1a8e222017da' User entered 'No (N)'	System	25 Aug 2020 13:52:57
	System	25 Aug 2020 13:52:57

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dc15dd09-950e-4f07-b209-1a8e222017da'	System	25 Aug 2020 13:52:57
User entered 'None (1)'	System	25 Aug 2020 13:52:57

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:51', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dc15dd09-950e-4f07-b209-1a8e222017da' User entered '25 Aug 2020 09:52'	System	25 Aug 2020 13:52:57
	System	25 Aug 2020 13:52:57

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 2'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:30', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1661a478-eced-4b55-b9f8-d050d97e3da8'	System	26 Aug 2020 13:37:52
User entered 'None (1)'	System	26 Aug 2020 13:37:52

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:33', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1661a478-eced-4b55-b9f8-d050d97e3da8' User entered 'No (N)'	System	26 Aug 2020 13:37:52
	System	26 Aug 2020 13:37:52

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1661a478-eced-4b55-b9f8-d050d97e3da8'	System	26 Aug 2020 13:37:52
User entered 'No (N)'	System	26 Aug 2020 13:37:52

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1661a478-eced-4b55-b9f8-d050d97e3da8' User entered 'None (1)'	System	26 Aug 2020 13:37:52
	System	26 Aug 2020 13:37:52

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:50', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1661a478-eced-4b55-b9f8-d050d97e3da8' User entered '26 Aug 2020 09:37'	System	26 Aug 2020 13:37:52
	System	26 Aug 2020 13:37:52

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 3'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:33', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1f406a5a-8fcc-4aab-8f03-bcc37090670c'	System	27 Aug 2020 13:53:45
User entered 'None (1)'	System	27 Aug 2020 13:53:45

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:35', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1f406a5a-8fcc-4aab-8f03-bcc37090670c' User entered 'No (N)'	System	27 Aug 2020 13:53:45
	System	27 Aug 2020 13:53:45

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:37', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1f406a5a-8fcc-4aab-8f03-bcc37090670c' User entered 'No (N)'	System	27 Aug 2020 13:53:45
	System	27 Aug 2020 13:53:45

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:39', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1f406a5a-8fcc-4aab-8f03-bcc37090670c'	System	27 Aug 2020 13:53:45
User entered 'None (1)'	System	27 Aug 2020 13:53:45

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:41', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1f406a5a-8fcc-4aab-8f03-bcc37090670c' User entered '27 Aug 2020 09:53'	System	27 Aug 2020 13:53:45
	System	27 Aug 2020 13:53:45

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 4'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 5'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:23', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '6f077ebd-7d8f-406f-8b3b-8f186022263c'	System	28 Aug 2020 20:11:48
User entered 'None (1)'	System	28 Aug 2020 20:11:48

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:36', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '6f077ebd-7d8f-406f-8b3b-8f186022263c' User entered 'No (N)'	System	28 Aug 2020 20:11:48
	System	28 Aug 2020 20:11:48

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:42', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '6f077ebd-7d8f-406f-8b3b-8f186022263c' User entered 'No (N)'	System	28 Aug 2020 20:11:48
	System	28 Aug 2020 20:11:48

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '6f077ebd-7d8f-406f-8b3b-8f186022263c'	System	28 Aug 2020 20:11:48
User entered 'None (1)'	System	28 Aug 2020 20:11:48

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:46', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '6f077ebd-7d8f-406f-8b3b-8f186022263c' User entered '28 Aug 2020 16:11'	System	28 Aug 2020 20:11:48
	System	28 Aug 2020 20:11:48

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 6'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:04', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd06b837e-169a-41d9-9f83-93d630e6baf6'	System	29 Aug 2020 17:10:15
User entered 'None (1)'	System	29 Aug 2020 17:10:15

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:06', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd06b837e-169a-41d9-9f83-93d630e6baf6' User entered 'No (N)'	System	29 Aug 2020 17:10:15
	System	29 Aug 2020 17:10:15

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:08', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd06b837e-169a-41d9-9f83-93d630e6baf6' User entered 'No (N)'	System	29 Aug 2020 17:10:15
	System	29 Aug 2020 17:10:15

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:10', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd06b837e-169a-41d9-9f83-93d630e6baf6'	System	29 Aug 2020 17:10:15
User entered 'None (1)'	System	29 Aug 2020 17:10:15

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd06b837e-169a-41d9-9f83-93d630e6baf6' User entered '29 Aug 2020 13:10'	System	29 Aug 2020 17:10:15
	System	29 Aug 2020 17:10:15

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 7'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:18:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '2fa570aa-4a64-48f3-b8df-891f3d48c6e3'	System	31 Aug 2020 13:19:16
User entered 'None (1)'	System	31 Aug 2020 13:19:16

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:01', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '2fa570aa-4a64-48f3-b8df-891f3d48c6e3' User entered 'No (N)'	System	31 Aug 2020 13:19:16
	System	31 Aug 2020 13:19:16

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:04', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '2fa570aa-4a64-48f3-b8df-891f3d48c6e3' User entered 'No (N)'	System	31 Aug 2020 13:19:16
	System	31 Aug 2020 13:19:16

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:06', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '2fa570aa-4a64-48f3-b8df-891f3d48c6e3'	System	31 Aug 2020 13:19:16
User entered 'None (1)'	System	31 Aug 2020 13:19:16

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:08', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '2fa570aa-4a64-48f3-b8df-891f3d48c6e3'	System	31 Aug 2020 13:19:16
User entered '31 Aug 2020 09:19'	System	31 Aug 2020 13:19:16

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered 'None (0)'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:45', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered 'None (0)'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered 'None (0)'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:50', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered 'None (0)'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:53', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered 'None (0)'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:56', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered 'None (0)'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:14:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7'	System	24 Aug 2020 15:15:05
User entered 'No (N)'	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-24T11:15:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '436c4a2d-6fa0-4861-af2a-5a88e139f7b7' User entered '24 Aug 2020 11:15'	System	24 Aug 2020 15:15:05
	System	24 Aug 2020 15:15:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 10:48'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 13:18'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:55', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c' User entered 'None (0)'	System	25 Aug 2020 13:53:17
	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:52:58', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c'	System	25 Aug 2020 13:53:17
User entered 'No interference with activity (1)'	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:53:01', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c' User entered 'None (0)'	System	25 Aug 2020 13:53:17
	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:53:03', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c' User entered 'None (0)'	System	25 Aug 2020 13:53:17
	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:53:05', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c' User entered 'None (0)'	System	25 Aug 2020 13:53:17
	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:53:07', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c' User entered 'None (0)'	System	25 Aug 2020 13:53:17
	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:53:11', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c'	System	25 Aug 2020 13:53:17
User entered 'No (N)'	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-25T09:53:13', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '9bc9b1f0-38d7-4cfc-9f1f-d831746a3f4c' User entered '25 Aug 2020 09:53'	System	25 Aug 2020 13:53:17
	System	25 Aug 2020 13:53:17

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 2'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0' User entered 'None (0)'	System	26 Aug 2020 13:38:15
	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:37:57', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0'	System	26 Aug 2020 13:38:15
User entered 'No interference with activity (1)'	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:38:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0' User entered 'None (0)'	System	26 Aug 2020 13:38:15
	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:38:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0' User entered 'None (0)'	System	26 Aug 2020 13:38:15
	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:38:04', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0' User entered 'None (0)'	System	26 Aug 2020 13:38:15
	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:38:06', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0' User entered 'None (0)'	System	26 Aug 2020 13:38:15
	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:38:09', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0'	System	26 Aug 2020 13:38:15
User entered 'No (N)'	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-26T09:38:11', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '17231b4f-c1ba-4c30-91b7-723921c421f0' User entered '26 Aug 2020 09:38'	System	26 Aug 2020 13:38:15
	System	26 Aug 2020 13:38:15

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 3'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:46', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750' User entered 'None (0)'	System	27 Aug 2020 13:54:05
	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750' User entered 'None (0)'	System	27 Aug 2020 13:54:05
	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:50', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750' User entered 'None (0)'	System	27 Aug 2020 13:54:05
	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:51', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750' User entered 'None (0)'	System	27 Aug 2020 13:54:05
	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:53', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750' User entered 'None (0)'	System	27 Aug 2020 13:54:05
	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:55', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750'	System	27 Aug 2020 13:54:05
User entered 'None (0)'	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:53:58', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750' User entered 'No (N)'	System	27 Aug 2020 13:54:05
	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-27T09:54:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8a3418dd-16f8-4139-b1f2-df817a9cc750'	System	27 Aug 2020 13:54:05
User entered '27 Aug 2020 09:54'	System	27 Aug 2020 13:54:05

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 4'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 5'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered 'None (0)'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:50', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered 'None (0)'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:52', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered 'None (0)'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:53', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered 'None (0)'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered 'None (0)'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:55', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered 'None (0)'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:57', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6'	System	28 Aug 2020 20:12:02
User entered 'No (N)'	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-28T16:11:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f136d766-dae5-495f-a89f-56f2936206d6' User entered '28 Aug 2020 16:11'	System	28 Aug 2020 20:12:02
	System	28 Aug 2020 20:12:02

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 6'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:15', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'None (0)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:17', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'None (0)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:18', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'None (0)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:19', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'None (0)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:21', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'None (0)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:23', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'None (0)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered 'No (N)'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-29T13:10:27', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ee9ae26-9040-4ef8-9d26-cb06d13d4acc' User entered '29 Aug 2020 13:10'	System	29 Aug 2020 17:10:29
	System	29 Aug 2020 17:10:29

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 7'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:19', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'None (0)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:22', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'None (0)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:24', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'None (0)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'None (0)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:27', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'None (0)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:33', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'None (0)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:42', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered 'No (N)'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-08-31T09:19:45', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '00a0c549-e3e6-4433-9f76-32f02e0bc0d8' User entered '31 Aug 2020 09:19'	System	31 Aug 2020 13:19:47
	System	31 Aug 2020 13:19:47

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:11:28

US3052295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:57
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:56:41

US3052295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:57
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:21:57
User entered '1 Sep 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:58:31
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed date' (Site from System).	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:57:19
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Oct 2020 17:56:41
User entered '14 Sep 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:56:41

US3052295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:57
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:56:41

US3052295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:57
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:56:41

US3052295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:19:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	23 Sep 2020 18:26:28

US3052295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	23 Sep 2020 18:26:28

US3052295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:58:59

US3052295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
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)	22 Oct 2020 16:09:11
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 'confirmed' (Site from System).	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:59:10
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	20 Oct 2020 17:58:59
User entered '14 Sep 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 17:58:59

US3052295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:58:59

US3052295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 17:58:59

US3052295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	23 Sep 2020 18:26:36

US3052295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	23 Sep 2020 18:26:36

US3052295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:00:56

US3052295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:00:56

US3052295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:00:56

US3052295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:00:56

US3052295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:57
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:26:58

US3052295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	23 Sep 2020 18:26:58

US3052295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:10:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:27:10

US3052295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:10:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:27:10

US3052295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[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 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:10:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:27:10

US3052295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'VISIT2'	System	23 Sep 2020 18:27:10

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Pre-Dose (PREDOSE)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Sep 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '13:20'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '23 Sep 2020 13:20'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '99' F	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Oral (Oral)'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '74'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'bpm'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '12'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'breaths/min'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '127'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '64'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Post-Dose (POSTDOSE)'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Sep 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '14:32'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '23 Sep 2020 14:32'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '98.5' F	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Oral (Oral)'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '71'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'bpm'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '14'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'breaths/min'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '116'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '76'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	29 Sep 2020 15:30:44

US3052295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:29
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:27:19

US3052295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:29
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:27:19

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '14:02'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '23 Sep 2020 14:02'	System	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.		07 Apr 2021 20:11:40
User entered 'ONCE'	System	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 18:28:34

US3052295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:46
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:32:17

US3052295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:46
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 04:27:14
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'collection shipped' (Site from DM).	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:50:18
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:22:11
User entered '23 Sep 2020'	Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:32:17

US3052295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:46
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '13:30'	(b) (4) Nicole Davis (b) (4) (b) (4)	29 Sep 2020 15:32:17

US3052295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '23 Sep 2020 13:30'	System	29 Sep 2020 15:32:17

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '13:32'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '23 Sep 2020 13:32'	System	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:11:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered empty.	System	20 Oct 2020 18:02:14

US3052295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:13:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:02:22

US3052295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	20 Oct 2020 18:02:22

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:30:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd87caef5-2cf6-4936-a823-197bae8d30f3' User entered 'Yes (Y)'	System	23 Sep 2020 18:30:44
	System	23 Sep 2020 18:30:44

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:30:29', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd87caef5-2cf6-4936-a823-197bae8d30f3' User entered '98.5'	System	23 Sep 2020 18:30:44
	System	23 Sep 2020 18:30:44

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:30:35', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd87caef5-2cf6-4936-a823-197bae8d30f3'	System	23 Sep 2020 18:30:44
User entered 'No (N)'	System	23 Sep 2020 18:30:44

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:30:41', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd87caef5-2cf6-4936-a823-197bae8d30f3'	System	23 Sep 2020 18:30:44
User entered '23 Sep 2020 14:30'	System	23 Sep 2020 18:30:44

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 14:22'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 16:52'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 17:47'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 2'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:23:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '99d186ca-6dac-4a16-bca2-95adc3e9eee9' User entered 'Yes (Y)'	System	24 Sep 2020 17:24:08
	System	24 Sep 2020 17:24:08

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:23:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '99d186ca-6dac-4a16-bca2-95adc3e9eee9' User entered '97.7'	System	24 Sep 2020 17:24:08
	System	24 Sep 2020 17:24:08

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:23:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '99d186ca-6dac-4a16-bca2-95adc3e9eee9' User entered 'Yes (Y)'	System	24 Sep 2020 17:24:08
	System	24 Sep 2020 17:24:08

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
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 'discussed symptoms but did not indicate having taken medication ' (Site from System).		06 Apr 2021 09:30:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:23:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '99d186ca-6dac-4a16-bca2-95adc3e9eee9'	System	24 Sep 2020 17:24:08
User entered '1'	System	24 Sep 2020 17:24:08

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:23:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '99d186ca-6dac-4a16-bca2-95adc3e9eee9' User entered '0'	System	24 Sep 2020 17:24:08
	System	24 Sep 2020 17:24:08

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '99d186ca-6dac-4a16-bca2-95adc3e9eee9' User entered '24 Sep 2020 13:24'	System	24 Sep 2020 17:24:08
	System	24 Sep 2020 17:24:08

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 3'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 4'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:30:44', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f021fa89-34b2-4419-9933-eb39f2bed53a' User entered 'Yes (Y)'	System	26 Sep 2020 17:31:01
	System	26 Sep 2020 17:31:01

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:30:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f021fa89-34b2-4419-9933-eb39f2bed53a' User entered '98.2'	System	26 Sep 2020 17:31:01
	System	26 Sep 2020 17:31:01

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:30:52', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f021fa89-34b2-4419-9933-eb39f2bed53a'	System	26 Sep 2020 17:31:01
User entered 'Yes (Y)'	System	26 Sep 2020 17:31:01

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
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 'discussed symptoms but did not indicate having taken medication ' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:53:39
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	26 Sep 2020 17:31:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:30:56', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f021fa89-34b2-4419-9933-eb39f2bed53a'	System	26 Sep 2020 17:31:01
User entered '1'	System	26 Sep 2020 17:31:01

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:30:56', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f021fa89-34b2-4419-9933-eb39f2bed53a' User entered '0'	System	26 Sep 2020 17:31:01
	System	26 Sep 2020 17:31:01

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:30:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f021fa89-34b2-4419-9933-eb39f2bed53a' User entered '26 Sep 2020 13:30'	System	26 Sep 2020 17:31:01
	System	26 Sep 2020 17:31:01

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 5'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 6'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:13:59', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '31636a43-5069-4cb7-8ff9-e58130243ddf' User entered 'No (N)'	System	29 Sep 2020 11:14:13
	System	29 Sep 2020 11:14:13

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '31636a43-5069-4cb7-8ff9-e58130243ddf' User entered 'Yes (Y)'	System	29 Sep 2020 11:14:13
	System	29 Sep 2020 11:14:13

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
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 'discussed symptoms but did not indicate having taken medication ' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:54:11
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	29 Sep 2020 11:14:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:07', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '31636a43-5069-4cb7-8ff9-e58130243ddf'	System	29 Sep 2020 11:14:13
User entered '1'	System	29 Sep 2020 11:14:13

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:07', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '31636a43-5069-4cb7-8ff9-e58130243ddf' User entered '0'	System	29 Sep 2020 11:14:13
	System	29 Sep 2020 11:14:13

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:11', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '31636a43-5069-4cb7-8ff9-e58130243ddf' User entered '29 Sep 2020 07:14'	System	29 Sep 2020 11:14:13
	System	29 Sep 2020 11:14:13

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 7'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:30:53', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '54906b1c-2929-4289-80f3-c76ffe5d866b'	System	23 Sep 2020 18:31:12
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 18:31:12

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:30:57', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '54906b1c-2929-4289-80f3-c76ffe5d866b' User entered 'No (N)'	System	23 Sep 2020 18:31:12
	System	23 Sep 2020 18:31:12

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:01', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '54906b1c-2929-4289-80f3-c76ffe5d866b' User entered 'No (N)'	System	23 Sep 2020 18:31:12
	System	23 Sep 2020 18:31:12

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:05', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '54906b1c-2929-4289-80f3-c76ffe5d866b'	System	23 Sep 2020 18:31:12
User entered 'None (1)'	System	23 Sep 2020 18:31:12

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:08', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '54906b1c-2929-4289-80f3-c76ffe5d866b' User entered '23 Sep 2020 14:31'	System	23 Sep 2020 18:31:12
	System	23 Sep 2020 18:31:12

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 14:22'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 16:52'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 17:47'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 2'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:09', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a7403205-79cd-4a6b-bf31-619a6da2412f' User entered 'None (1)'	System	24 Sep 2020 17:24:33
	System	24 Sep 2020 17:24:33

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a7403205-79cd-4a6b-bf31-619a6da2412f' User entered 'No (N)'	System	24 Sep 2020 17:24:33
	System	24 Sep 2020 17:24:33

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:22', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a7403205-79cd-4a6b-bf31-619a6da2412f' User entered 'No (N)'	System	24 Sep 2020 17:24:33
	System	24 Sep 2020 17:24:33

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a7403205-79cd-4a6b-bf31-619a6da2412f' User entered 'None (1)'	System	24 Sep 2020 17:24:33
	System	24 Sep 2020 17:24:33

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:28', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a7403205-79cd-4a6b-bf31-619a6da2412f' User entered '24 Sep 2020 13:24'	System	24 Sep 2020 17:24:33
	System	24 Sep 2020 17:24:33

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 3'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 4'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'c9eef4b3-891f-45d0-9c03-779c1dc4ce6f'	System	26 Sep 2020 17:32:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Sep 2020 17:32:08

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:51', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'c9eef4b3-891f-45d0-9c03-779c1dc4ce6f' User entered 'No (N)'	System	26 Sep 2020 17:32:08
	System	26 Sep 2020 17:32:08

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'c9eef4b3-891f-45d0-9c03-779c1dc4ce6f' User entered 'No (N)'	System	26 Sep 2020 17:32:08
	System	26 Sep 2020 17:32:08

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:32:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'c9eef4b3-891f-45d0-9c03-779c1dc4ce6f'	System	26 Sep 2020 17:32:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	26 Sep 2020 17:32:08

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:32:05', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'c9eef4b3-891f-45d0-9c03-779c1dc4ce6f' User entered '26 Sep 2020 13:32'	System	26 Sep 2020 17:32:08
	System	26 Sep 2020 17:32:08

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 5'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 6'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:17', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ee3ad91f-a538-41f5-9730-0e3d52cab525'	System	29 Sep 2020 11:14:36
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:20', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ee3ad91f-a538-41f5-9730-0e3d52cab525'	System	29 Sep 2020 11:14:36
User entered 'No (N)'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:24', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ee3ad91f-a538-41f5-9730-0e3d52cab525'	System	29 Sep 2020 11:14:36
User entered 'No (N)'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:29', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ee3ad91f-a538-41f5-9730-0e3d52cab525'	System	29 Sep 2020 11:14:36
User entered 'None (1)'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:31', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ee3ad91f-a538-41f5-9730-0e3d52cab525' User entered '29 Sep 2020 07:14'	System	29 Sep 2020 11:14:36
	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 7'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155' User entered 'None (0)'	System	23 Sep 2020 18:31:34
	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:17', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155'	System	23 Sep 2020 18:31:34
User entered 'None (0)'	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:20', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155' User entered 'None (0)'	System	23 Sep 2020 18:31:34
	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:21', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155' User entered 'None (0)'	System	23 Sep 2020 18:31:34
	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:23', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155' User entered 'None (0)'	System	23 Sep 2020 18:31:34
	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155' User entered 'None (0)'	System	23 Sep 2020 18:31:34
	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:28', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155'	System	23 Sep 2020 18:31:34
User entered 'No (N)'	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-23T14:31:30', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'f4dfc69b-a8bb-4ef9-b0ad-c48d8453b155'	System	23 Sep 2020 18:31:34
User entered '23 Sep 2020 14:31'	System	23 Sep 2020 18:31:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 14:22'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 16:52'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '23 Sep 2020 17:47'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 2'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:42', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:45', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered 'Some interference with activity (2)'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:52', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered 'Some interference with activity (2)'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:24:58', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7' User entered 'None (0)'	System	24 Sep 2020 17:25:27
	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:25:06', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:25:16', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered 'Some interference with activity not requiring medical attention (2)'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:25:23', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered 'No (N)'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-24T13:25:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '7ffe10b1-db34-48d6-9914-bfe5e550efd7'	System	24 Sep 2020 17:25:27
User entered '24 Sep 2020 13:25'	System	24 Sep 2020 17:25:27

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 3'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 4'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:13', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8'	System	26 Sep 2020 17:31:41
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:15', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8'	System	26 Sep 2020 17:31:41
User entered 'Significant; prevents daily activity (3)'	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:20', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8' User entered 'Significant; prevents daily activity (3)'	System	26 Sep 2020 17:31:41
	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:22', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8' User entered 'Significant; prevents daily activity (3)'	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:25', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8'	System	26 Sep 2020 17:31:41
User entered 'Prevents daily activity, requires outpatient IV hydration (3)'	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:30', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8'	System	26 Sep 2020 17:31:41
User entered 'Prevents daily activity and requires medical attention (3)'	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:34', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8' User entered 'Yes (Y)'	System	26 Sep 2020 17:31:41
	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-26T13:31:38', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '3d244822-dcc8-4b20-8c3b-5e7fb7a476f8' User entered '26 Sep 2020 13:31'	System	26 Sep 2020 17:31:41
	System	26 Sep 2020 17:31:41

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 5'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 6'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:45', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:14:58', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:15:02', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Prevents daily activity, requires outpatient IV hydration (3)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:15:07', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Prevents daily activity and requires medical attention (3)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:15:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507'	System	29 Sep 2020 11:15:16
User entered 'Yes (Y)'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-09-29T07:15:14', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8ae99367-e8c3-404b-b102-e69c84fd8507' User entered '29 Sep 2020 07:15'	System	29 Sep 2020 11:15:16
	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	23 Sep 2020 18:28:34
User entered 'Day 7'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 18:28:34

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:14:36
User entered 'Day 8'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:15:16
User entered 'Day 8'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:25

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:15:16
User entered 'Day 8'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:57:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:15:16
User entered 'Day 8'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:15:16
User entered 'Day 8'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

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 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:15:16
User entered 'Day 8'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:57:25

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:15:16
User entered 'Day 8'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 14:57:25

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:15:16

US3052295

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
Data entry locked.	System	29 Sep 2020 11:14:36
User entered 'Day 8'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:25

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02

US3052295

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 11:14:36

US3052295

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 11:14:36

US3052295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:03:14

US3052295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:03:14

US3052295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:03:14

US3052295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:03:14

US3052295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:03:21

US3052295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	20 Oct 2020 18:03:21

US3052295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:09

US3052295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:36
User closed query 'Per source, contact made on 08Oct2020. Please use this date is source is correct. If correct please update the below fields.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:24:30
Query 'Per source, contact made on 08Oct2020. Please use this date is source is correct. If correct please update the below fields.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:37:55
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 16:37:49
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:37:49
User opened query 'Per source, contact made on 08Oct2020. Please use this date is source is correct. If correct please update the below fields.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:24:48
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '07 Oct 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:09

US3052295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:09

US3052295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'VM left'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:09

US3052295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:16

US3052295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	20 Oct 2020 18:04:16

US3052295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:25:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:54

US3052295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:25:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '14 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:54

US3052295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:25:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:54

US3052295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:25:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 18:04:54

US3052295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:25:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 18:05:01

US3052295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	20 Oct 2020 18:05:01

US3052295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:37:08

US3052295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
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)	
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).	(b) (4), (b) (6)	02 Dec 2020 06:09:47
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	Avia McClain-Stocker	01 Dec 2020 20:37:17
User entered '30 Nov 2020'	(b) (4)	
	System	01 Dec 2020 20:37:08
	Avia McClain-Stocker	01 Dec 2020 20:37:08
	(b) (4)	

US3052295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

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 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Clinic (Clinic)'	Avia McClain-Stocker (b) (4)	01 Dec 2020 20:37:08

US3052295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'VISIT3'	System	01 Dec 2020 20:37:08

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '30 Nov 2020'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '08:43'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '30 Nov 2020 08:43'	System	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '98.2' F	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '63'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'bpm'	System	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '14'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'breaths/min'	System	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '127'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '78'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'mmHg'	System	01 Dec 2020 20:38:50

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54

US3052295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54

US3052295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4)	16 Apr 2021 15:24:15
User closed query 'Per source, PE not completed.' (Site from CRA).	(b) (4)	16 Apr 2021 15:23:36
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per source, PE not completed.' answered with 'ddone' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:39:03
Signature has been broken.	(b) (4)	09 Apr 2021 16:38:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 16:38:58
User opened query 'Per source, PE not completed.' (Site from CRA).	(b) (4)	07 Apr 2021 20:30:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:37:53

US3052295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:15
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:38:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:38:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '30 Nov 2020'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:37:53

US3052295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User closed query 'Per GCL Lab recon: Immunogenicity: PPD has two Immuno sample dated 30NOV2020 Barcode: 1F657080013 labelled as UNSCHEDULED visit and other 30NOV2020 Barcode: 1F653456965 labelled as Visit 3 DAY 57. Please review both the Barcode in Preclarus and confirm the correct Barcode for this visit and the correct subject to which the other sample belongs. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 12:34:01
DataPoint Verified.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
Query 'Per GCL Lab recon: Immunogenicity: PPD has two Immuno sample dated 30NOV2020 Barcode: 1F657080013 labelled as UNSCHEDULED visit and other 30NOV2020 Barcode: 1F653456965 labelled as Visit 3 DAY 57. Please review both the Barcode in Preclarus and confirm the correct Barcode for this visit and the correct subject to which the other sample belongs. Thank you.' answered with 'both belong to subject 3052295' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 20:30:27
User opened query 'Per GCL Lab recon: Immunogenicity: PPD has two Immuno sample dated 30NOV2020 Barcode: 1F657080013 labelled as UNSCHEDULED visit and other 30NOV2020 Barcode: 1F653456965 labelled as Visit 3 DAY 57. Please review both the Barcode in Preclarus and confirm the correct Barcode for this visit and the correct subject to which the other sample belongs. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:14:58
Query 'Per GCL Lab recon: Immunogenicity: PPD has two Immuno sample dated 30NOV2020 Barcode: 1F657080013 labelled as UNSCHEDULED visit and other 30NOV2020 Barcode: 1F653456965 labelled as Visit 3 DAY. Please review both the Barcode in Preclarus and confirm the correct Barcode for this visit and the correct subject to which the other sample belongs. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:29:50
	(b) (4), (b) (6)	23 Mar 2021 09:29:31

US3052295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:30:27
Query 'Per GCL Lab recon (LB4) - IMMUNO 5 Sample dated 30 NOV 2020 is reported under Visit 3 Day 57 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit with date in the response and update if applicable in EDC or PPD portal accordingly or provide clarification. Thank you.		23 Mar 2021 09:29:12
' canceled (Site from DM).		
User opened query 'Per GCL Lab recon (LB4) - IMMUNO 5 Sample dated 30 NOV 2020 is reported under Visit 3 Day 57 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit with date in the response and update if applicable in EDC or PPD portal accordingly or provide clarification. Thank you.	(b) (4), (b) (6)	03 Mar 2021 18:23:22
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30NOV2020 is recorded under Visit 3 Day 57visit 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. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:31:03

US3052295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30NOV2020 is recorded under Visit 3 Day 57visit 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). User entered '30 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 13:03:52
	Avia McClain-Stocker	01 Dec 2020 20:37:39
	(b) (4)	

US3052295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	07 Apr 2021 20:30:27
User entered '09:12'	(b) (4), (b) (6)	01 Dec 2020 20:37:39
	Avia McClain-Stocker	
	(b) (4)	

US3052295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '30 Nov 2020 09:12'	System	01 Dec 2020 20:37:39

US3052295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:30:31
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	01 Dec 2020 20:38:01

US3052295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered '1'	System	01 Dec 2020 20:38:01

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 64'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56
Data entry locked.	System	24 Aug 2020 15:11:28
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56
Data entry locked.	System	24 Aug 2020 15:11:28
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 71'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56
Data entry locked.	System	24 Aug 2020 15:11:28
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:37:56
Data entry locked.	System	24 Aug 2020 15:11:28
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
Data entry locked.	System	24 Aug 2020 15:11:28
User entered 'Day 78'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		16 Apr 2021 17:00:17
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'subject stated it was a follow up appointment, nothing was wrong. updated' (Site from DM).		14 Apr 2021 15:49:21
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		30 Nov 2020 14:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-11-10T13:39:51', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8c3b72bf-2308-4eef-80ea-69a9a5079456'	System	10 Nov 2020 18:40:26
User entered 'Yes (Y)'	System	10 Nov 2020 18:40:26

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-11-10T13:39:56', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8c3b72bf-2308-4eef-80ea-69a9a5079456'	System	10 Nov 2020 18:40:26
User entered 'No (N)'	System	10 Nov 2020 18:40:26

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-11-10T13:40:01', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8c3b72bf-2308-4eef-80ea-69a9a5079456'	System	10 Nov 2020 18:40:26
User entered 'No (N)'	System	10 Nov 2020 18:40:26

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-11-10T13:40:05', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8c3b72bf-2308-4eef-80ea-69a9a5079456'	System	10 Nov 2020 18:40:26
User entered 'Yes (Y)'	System	10 Nov 2020 18:40:26

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-11-10T13:40:10', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8c3b72bf-2308-4eef-80ea-69a9a5079456'	System	10 Nov 2020 18:40:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 18:40:26

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-11-10T13:40:13', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '8c3b72bf-2308-4eef-80ea-69a9a5079456' User entered '10 Nov 2020 13:40:13'	System	10 Nov 2020 18:40:26
	System	10 Nov 2020 18:40:26

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
Data entry locked.	System	24 Aug 2020 15:11:28
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 15:11:28

US3052295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:41
Data entry locked.	System	24 Aug 2020 15:11:28
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 15:11:28

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-02T13:28:23', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'e291b995-9a27-4e99-93f2-1a6acce63ca8'	System	02 Dec 2020 18:28:54
User entered 'Yes (Y)'	System	02 Dec 2020 18:28:54

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-02T13:28:32', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'e291b995-9a27-4e99-93f2-1a6acce63ca8'	System	02 Dec 2020 18:28:54
User entered 'No (N)'	System	02 Dec 2020 18:28:54

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-02T13:28:37', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'e291b995-9a27-4e99-93f2-1a6acce63ca8' User entered 'No (N)'	System	02 Dec 2020 18:28:54
	System	02 Dec 2020 18:28:54

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-02T13:28:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'e291b995-9a27-4e99-93f2-1a6acce63ca8' User entered 'No (N)'	System	02 Dec 2020 18:28:54
	System	02 Dec 2020 18:28:54

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-02T13:28:52', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'e291b995-9a27-4e99-93f2-1a6acce63ca8' User entered '02 Dec 2020 13:28:52'	System	02 Dec 2020 18:28:54
	System	02 Dec 2020 18:28:54

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-18T12:35:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'bcfacf9a-5f8a-4729-add9-097c7d9ff54b'	System	18 Dec 2020 17:35:48
User entered 'No (N)'	System	18 Dec 2020 17:35:48

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-18T12:35:36', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'bcfacf9a-5f8a-4729-add9-097c7d9ff54b'	System	18 Dec 2020 17:35:48
User entered 'No (N)'	System	18 Dec 2020 17:35:48

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-18T12:35:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'bcfacf9a-5f8a-4729-add9-097c7d9ff54b' User entered '18 Dec 2020 12:35:43'	System	18 Dec 2020 17:35:48
	System	18 Dec 2020 17:35:48

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-25T12:10:54', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a566b464-699c-40ec-bc40-537f49ac2ddc' User entered 'No (N)'	System	25 Dec 2020 17:11:11
	System	25 Dec 2020 17:11:11

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-25T12:11:05', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a566b464-699c-40ec-bc40-537f49ac2ddc' User entered 'No (N)'	System	25 Dec 2020 17:11:11
	System	25 Dec 2020 17:11:11

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-25T12:11:09', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a566b464-699c-40ec-bc40-537f49ac2ddc' User entered '25 Dec 2020 12:11:09'	System	25 Dec 2020 17:11:11

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-31T16:44:08', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '89257a4c-86b3-4c76-8025-5e466c36cbcd' User entered 'No (N)'	System	31 Dec 2020 21:44:17
	System	31 Dec 2020 21:44:17

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-31T16:44:11', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '89257a4c-86b3-4c76-8025-5e466c36cbcd' User entered 'No (N)'	System	31 Dec 2020 21:44:17

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2020-12-31T16:44:15', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '89257a4c-86b3-4c76-8025-5e466c36cbcd' User entered '31 Dec 2020 16:44:15'	System	31 Dec 2020 21:44:17
	System	31 Dec 2020 21:44:17

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-20T06:10:04', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '5e859768-de10-40aa-bde8-cf42406623fe' User entered 'No (N)'	System	20 Jan 2021 11:10:19
	System	20 Jan 2021 11:10:19

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-20T06:10:13', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '5e859768-de10-40aa-bde8-cf42406623fe' User entered 'No (N)'	System	20 Jan 2021 11:10:19

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-20T06:10:16', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '5e859768-de10-40aa-bde8-cf42406623fe' User entered '20 Jan 2021 06:10:16'	System	20 Jan 2021 11:10:19
	System	20 Jan 2021 11:10:19

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-30T17:59:18', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a0a5bc95-bc6b-4ada-9e83-4c5074eb74f2'	System	30 Jan 2021 22:59:42
User entered 'No (N)'	System	30 Jan 2021 22:59:42

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-30T17:59:24', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a0a5bc95-bc6b-4ada-9e83-4c5074eb74f2' User entered 'Yes (Y)'	System	30 Jan 2021 22:59:42
	System	30 Jan 2021 22:59:42

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-30T17:59:28', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a0a5bc95-bc6b-4ada-9e83-4c5074eb74f2'	System	30 Jan 2021 22:59:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 22:59:42

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-01-30T17:59:31', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'a0a5bc95-bc6b-4ada-9e83-4c5074eb74f2' User entered '30 Jan 2021 17:59:31'	System	30 Jan 2021 22:59:42

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-03T16:26:27', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ff856af1-e03a-49ef-93ab-f165a54b4247' User entered 'No (N)'	System	03 Feb 2021 21:26:49
	System	03 Feb 2021 21:26:49

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-03T16:26:43', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ff856af1-e03a-49ef-93ab-f165a54b4247'	System	03 Feb 2021 21:26:49
User entered 'No (N)'	System	03 Feb 2021 21:26:49

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-03T16:26:46', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ff856af1-e03a-49ef-93ab-f165a54b4247' User entered '03 Feb 2021 16:26:46'	System	03 Feb 2021 21:26:49
	System	03 Feb 2021 21:26:49

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-12T12:00:36', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dbe5a9ab-a695-4794-a16a-0c44c320610c'	System	12 Feb 2021 17:03:43
User entered 'No (N)'	System	12 Feb 2021 17:03:43

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-12T12:00:38', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dbe5a9ab-a695-4794-a16a-0c44c320610c' User entered 'No (N)'	System	12 Feb 2021 17:03:43

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-12T12:00:42', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'dbe5a9ab-a695-4794-a16a-0c44c320610c' User entered '12 Feb 2021 12:00:42'	System	12 Feb 2021 17:03:43

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-25T16:49:42', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '68016c32-13e9-4056-ba03-5a8753103ad3' User entered 'No (N)'	System	26 Feb 2021 00:27:00
	System	26 Feb 2021 00:27:00

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-25T16:49:45', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '68016c32-13e9-4056-ba03-5a8753103ad3'	System	26 Feb 2021 00:27:00
User entered 'No (N)'	System	26 Feb 2021 00:27:00

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-02-25T16:49:48', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '68016c32-13e9-4056-ba03-5a8753103ad3'	System	26 Feb 2021 00:27:00
User entered '25 Feb 2021 16:49:48'	System	26 Feb 2021 00:27:00

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-03-18T19:55:51', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1e85d963-99e8-4c8a-84ff-49c9b57cbe64' User entered 'No (N)'	System	18 Mar 2021 23:55:59
	System	18 Mar 2021 23:55:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-03-18T19:55:53', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1e85d963-99e8-4c8a-84ff-49c9b57cbe64'	System	18 Mar 2021 23:55:59
User entered 'No (N)'	System	18 Mar 2021 23:55:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-03-18T19:55:56', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '1e85d963-99e8-4c8a-84ff-49c9b57cbe64' User entered '18 Mar 2021 19:55:56'	System	18 Mar 2021 23:55:59
	System	18 Mar 2021 23:55:59

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-02T17:15:08-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd57efc37-147c-4c0f-9303-a2b105a1b943'	System	02 Apr 2021 21:15:20
User entered 'No (N)'	System	02 Apr 2021 21:15:20

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-02T17:15:10-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd57efc37-147c-4c0f-9303-a2b105a1b943'	System	02 Apr 2021 21:15:20
User entered 'No (N)'	System	02 Apr 2021 21:15:20

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-02T17:15:13-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'd57efc37-147c-4c0f-9303-a2b105a1b943'	System	02 Apr 2021 21:15:20
User entered '02 Apr 2021 17:15:13'	System	02 Apr 2021 21:15:20

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-11T11:59:23-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'eb28fde8-7797-4def-b65c-7c160b7ea25e'	System	11 Apr 2021 15:59:36
User entered 'No (N)'	System	11 Apr 2021 15:59:36

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-11T11:59:26-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'eb28fde8-7797-4def-b65c-7c160b7ea25e'	System	11 Apr 2021 15:59:36
User entered 'No (N)'	System	11 Apr 2021 15:59:36

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-11T11:59:30-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'eb28fde8-7797-4def-b65c-7c160b7ea25e' User entered '11 Apr 2021 11:59:30'	System	11 Apr 2021 15:59:36
	System	11 Apr 2021 15:59:36

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-16T12:43:41-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ae934660-fbbe-40e4-abeb-b46207e1ab22'	System	16 Apr 2021 17:31:48
User entered 'No (N)'	System	16 Apr 2021 17:31:48

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-16T13:28:39-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ae934660-fbbe-40e4-abeb-b46207e1ab22'	System	16 Apr 2021 17:31:48
User entered 'No (N)'	System	16 Apr 2021 17:31:48

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-16T13:28:45-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: 'ae934660-fbbe-40e4-abeb-b46207e1ab22'	System	16 Apr 2021 17:31:48
User entered '16 Apr 2021 13:28:45'	System	16 Apr 2021 17:31:48

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-28T09:53:26-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '5ea24288-099a-4665-8185-b4a9a0183835'	System	29 Apr 2021 01:12:27
User entered 'No (N)'	System	29 Apr 2021 01:12:27

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-28T09:53:29-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '5ea24288-099a-4665-8185-b4a9a0183835'	System	29 Apr 2021 01:12:27
User entered 'No (N)'	System	29 Apr 2021 01:12:27

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-04-28T09:53:33-04:00', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '5ea24288-099a-4665-8185-b4a9a0183835'	System	29 Apr 2021 01:12:27
User entered '28 Apr 2021 09:53:33'	System	29 Apr 2021 01:12:27

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:37:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:37:56

US3052295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:37:56
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:37:56

US3052295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:57:25

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)	29 Apr 2021 12:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-03-08T15:41:12', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ed90f82-a527-4330-8256-227621a181a8'	System	08 Mar 2021 20:41:20
User entered 'No (N)'	System	08 Mar 2021 20:41:20

US3052295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:57:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C3F537CC-BD80-4033-BE57-F283AEDACE5A)', Time: '2021-03-08T15:41:18', User OID: 'PatientReportedOutcome (US3052295)', ODM File OID: '4ed90f82-a527-4330-8256-227621a181a8' User entered '08 Mar 2021 15:41:18'	System	08 Mar 2021 20:41:20
	System	08 Mar 2021 20:41:20

US3052295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:33
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:51:01

US3052295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:33
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:51:01

US3052295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:33
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:51:01

US3052295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:33
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:51:01

US3052295

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:36
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 14:26:00

US3052295

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:54
User entered 'I'	System	23 Dec 2020 14:26:00

US3052295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.		07 Apr 2021 20:32:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:26:36

US3052295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:32:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:26:36

US3052295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:32:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:26:36

US3052295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:32:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:26:36

US3052295

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:32:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	04 Jan 2021 01:23:33

US3052295

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
User entered 'I'	System	04 Jan 2021 01:23:33

US3052295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.		08 Apr 2021 20:42:54
Query 'Please provide source.' canceled (Site from CRA).		08 Apr 2021 20:42:52
User opened query 'Please provide source.' (Site from CRA).		07 Apr 2021 20:36:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:30:44

US3052295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:42:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 07:42:55
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'VERIFIED DATE OF CALL' (Site from System).	(b) (4), (b) (6)	14 Feb 2021 02:30:51
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	14 Feb 2021 02:30:44
User entered '05 Feb 2021'	(b) (4), (b) (6)	14 Feb 2021 02:30:44

US3052295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:42:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:30:44

US3052295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:42:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:30:44

US3052295

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:36:21
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:29:14

US3052295

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
User entered '1'	System	25 Feb 2021 18:29:14

US3052295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.		08 Apr 2021 21:17:20
Query 'Please provide source.' canceled (Site from CRA).		08 Apr 2021 21:17:17
User opened query 'Please provide source.' (Site from CRA).		07 Apr 2021 20:43:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:29:39

US3052295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04MAR2021 is recorded under Participant Decision Visit/OL-D1 in PPD Central lab, however the sample is missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:55:32
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04MAR2021 is recorded under Participant Decision Visit/OL-D1 in PPD Central lab, however the sample is missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'updated in edc' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:17:20
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04MAR2021 is recorded under Participant Decision Visit/OL-D1 in PPD Central lab, however the sample is missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:48:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered '22 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 18:29:39

US3052295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:17:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:29:39

US3052295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:17:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:48:16
User entered 'Left voicemail'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:29:39

US3052295

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	07 Apr 2021 20:43:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 15:20:42

US3052295

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:02
User entered 'I'	System	25 Mar 2021 15:20:42

US3052295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:41
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:10:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:10:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:10:40
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:26:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:26:38
User entered 'Yes (Y)'		25 Mar 2021 15:20:58

US3052295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:41
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) (6)	02 Apr 2021 20:36:04
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'confirmed and correct' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 13:10:54
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	01 Apr 2021 13:10:40
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:10:40
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:26:38
User entered '22 Mar 2021'		25 Mar 2021 15:20:58

US3052295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

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 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	07 Apr 2021 20:33:41
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:10:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:26:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Mar 2021 15:20:58

US3052295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered 'VISIT4'	System	01 Apr 2021 13:10:40
User entered empty.	System	25 Mar 2021 15:26:38
User entered 'VISIT4'	System	25 Mar 2021 15:20:58

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '04 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '10:11'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered '04 Mar 2021 10:11'	System	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '98.1' F	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '62'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered 'bpm'	System	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '12'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered 'breaths/min'	System	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '122'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered 'mmHg'	System	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:06
User entered '78'	(b) (4), (b) (6)	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered 'mmHg'	System	31 Mar 2021 15:29:57

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55

US3052295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55

US3052295

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:19
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:11:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:11:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:11:22
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:28:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:28:22
User entered 'Yes (Y)'		25 Mar 2021 15:21:05

US3052295

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:34:19
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:11:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:28:22
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:21:05

US3052295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:27
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:11:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:11:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:11:14
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:28:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:28:38
User entered 'Yes (Y)'		25 Mar 2021 15:21:35

US3052295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User closed query 'Per GCL Lab Recon: Sample dated 22Mar2021 for Visit 4 Day 209 has been reported in GCL, however, sample dated 04Mar2021 has been reported in EDC under Visit 4 day 209. Please reconcile and confirm correct date. Thanks. ' (Site from DM).		25 Apr 2021 11:54:07
Query 'Per GCL Lab Recon: Sample dated 22Mar2021 for Visit 4 Day 209 has been reported in GCL, however, sample dated 04Mar2021 has been reported in EDC under Visit 4 day 209. Please reconcile and confirm correct date. Thanks. ' answered with 'Confirmed date 04Mar2021' (Site from DM).		24 Apr 2021 16:18:38
User opened query 'Per GCL Lab Recon: Sample dated 22Mar2021 for Visit 4 Day 209 has been reported in GCL, however, sample dated 04Mar2021 has been reported in EDC under Visit 4 day 209. Please reconcile and confirm correct date. Thanks. ' (Site from DM).		21 Apr 2021 01:58:33
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:27
User entered '04 Mar 2021' reason for change: Data Entry Error		01 Apr 2021 13:11:14
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:28:38
User entered '22 Mar 2021'		25 Mar 2021 15:21:35

US3052295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:27
User entered '12:11' reason for change: Data Entry Error		01 Apr 2021 13:11:14
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:28:38
User entered '16:02'		25 Mar 2021 15:21:35

US3052295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered '04 Mar 2021 12:11'	System	01 Apr 2021 13:11:14
User entered empty.	System	25 Mar 2021 15:28:38
User entered '22 Mar 2021 16:02'	System	25 Mar 2021 15:21:35

US3052295

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:34:30
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 19:43:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 19:43:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:30
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:28:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:28:46
User entered 'Yes (Y)'		25 Mar 2021 15:21:39

US3052295

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:55
User entered '1'	System	30 Mar 2021 19:43:30
User entered empty.	System	25 Mar 2021 15:28:46
User entered '1'	System	25 Mar 2021 15:21:39

US3052295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 13:26:49

US3052295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:53
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:26:49

US3052295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:53
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:26:49

US3052295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:53
User entered 'Left voicemail'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:26:49

US3052295

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:26:54

US3052295

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 13:26:54

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:37:05
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:19:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:19:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:19:06
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:26:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:26:56
User entered 'Yes (Y)'		25 Mar 2021 15:22:14

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	07 Apr 2021 20:37:05
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:19:06
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:26:56
User entered '22 Mar 2021'		25 Mar 2021 15:22:14

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:28:16
DataPoint Verified.	(b) (4)	07 Apr 2021 20:37:05
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:19:06
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:26:56
User entered 'Clinic (Clinic)'		25 Mar 2021 15:22:14

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'UNBLND_DECIDE'	System	01 Apr 2021 13:19:06
User entered empty.	System	25 Mar 2021 15:26:56
User entered 'UNBLND_DECIDE'	System	25 Mar 2021 15:22:14

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:34:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 15:27:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 15:27:29
User entered ' 2021' (non-conformant).	(b) (4), (b) (6)	25 Mar 2021 15:27:29
User entered '22 Mar 2021'		25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 15:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:34:02
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:27:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:29
User entered 'Yes (Y)'		25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 15:34:11
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:34:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:29
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per source, subject was on placebos for both injections. Please review and reconcile.' canceled (Site from CRA).	(b) (4)	07 Apr 2021 20:38:41
User opened query 'Per source, subject was on placebos for both injections. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:38:33
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:34:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:29
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.		16 Apr 2021 15:22:32
User closed query ' Per source, subject was on placebos for both injections. Please review and reconcile.' (Site from CRA).		16 Apr 2021 15:22:27
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query ' Per source, subject was on placebos for both injections. Please review and reconcile.' answered with 'updated' (Site from CRA).	(b) (4)	(b) (4), (b) (6) 09 Apr 2021 16:30:11
User entered 'Placebo (Placebo)' reason for change: Data Entry Error		09 Apr 2021 16:30:03
User opened query ' Per source, subject was on placebos for both injections. Please review and reconcile.' (Site from CRA).		07 Apr 2021 20:38:45
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error		31 Mar 2021 15:34:02
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:27:29
User entered 'mRNA-1273 (mRNA-1273)'		25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.		16 Apr 2021 15:22:32
User closed query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).		12 Apr 2021 07:12:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:30:22
User opened query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).		09 Apr 2021 16:30:03
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error		08 Apr 2021 11:49:19
User entered empty; reason for change Data Entry Error		31 Mar 2021 15:34:02
User entered 'mRNA-1273 (mRNA-1273)'		25 Mar 2021 15:27:29
		25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.		16 Apr 2021 15:22:32
User closed query 'Per IRT, this subject received placebo for Day 29 Dosing. Please update data else clarify.' (Site from DM).		12 Apr 2021 07:12:55
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per IRT, this subject received placebo for Day 29 Dosing. Please update data else clarify.' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:30:28
User opened query 'Per IRT, this subject received placebo for Day 29 Dosing. Please update data else clarify.' (Site from DM).		09 Apr 2021 16:30:03
User entered 'Not Administered (NA)' reason for change: Data Entry Error		08 Apr 2021 11:29:25
User entered empty; reason for change Data Entry Error		31 Mar 2021 15:34:02
User entered 'mRNA-1273 (mRNA-1273)'		25 Mar 2021 15:27:29
		25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 15:34:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:29
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '1'	System	09 Apr 2021 16:30:03
User entered empty.	System	25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'I'	System	31 Mar 2021 15:34:02
User entered empty.	System	25 Mar 2021 15:23:10

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '168' cm		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '90' kg		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '31.88776'	System	31 Mar 2021 15:36:02
DataPoint set to visible.	System	31 Mar 2021 15:34:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered '168' cm	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 20:41:03
User entered '90' kg		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '31.88776'	System	31 Mar 2021 15:36:02
DataPoint set to visible.	System	31 Mar 2021 15:34:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User accepted default value 'Pre-Dose (PREDOSE)'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered 'Yes (Y)'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '04 Mar 2021'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.		16 Apr 2021 15:22:55
User closed query 'Per source, time of assessment was 10:11. Please review and reconcile.' (Site from CRA).		16 Apr 2021 15:22:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per source, time of assessment was 10:11. Please review and reconcile.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:31:32
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:31:22
User entered '10:11' reason for change: Data Entry Error		09 Apr 2021 16:31:22
DataPoint Verified.		07 Apr 2021 20:41:03
User opened query 'Per source, time of assessment was 10:11. Please review and reconcile.' (Site from CRA).		07 Apr 2021 20:40:13
User entered '10:05'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '04 Mar 2021 10:11'	System	09 Apr 2021 16:31:22
User entered '04 Mar 2021 10:05'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 20:41:03
User entered '98.1' F		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered '62'	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'bpm'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '12'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'breaths/min'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '122'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'mmHg'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '78'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'mmHg'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '168' cm		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '90' kg		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '31.88776'	System	31 Mar 2021 15:36:02
DataPoint set to visible.	System	31 Mar 2021 15:34:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User accepted default value 'Post-Dose (POSTDOSE)'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered 'Yes (Y)'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '04 Mar 2021'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered '12:47'	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '04 Mar 2021 12:47'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered '98.1' F	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered 'Oral (Oral)'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered empty.		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '76'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'bpm'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:03
User entered '14'	(b) (4), (b) (6)	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'breaths/min'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '175'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'mmHg'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:41:03
User entered '68'		31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'mmHg'	System	31 Mar 2021 15:36:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 15:36:12

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:41:20
User entered '04 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 15:36:12

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:42:00
User entered 'Yes (Y)'		31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:42:00
User entered empty.		31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:42:00
User entered empty.		31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'mRNA-1273'	System	31 Mar 2021 15:36:39
DataPoint set to visible.	System	31 Mar 2021 15:34:02

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:00
User entered '04 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.		16 Apr 2021 15:22:41
User closed query 'Per source, subject was dosed at 12:13. Please review and reconcile.' (Site from CRA)		16 Apr 2021 15:22:39
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per source, subject was dosed at 12:13. Please review and reconcile.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:32:30
User entered '12:13' reason for change: Data Entry Error		09 Apr 2021 16:32:22
DataPoint Un-verified.		07 Apr 2021 20:42:04
DataPoint Verified.		07 Apr 2021 20:42:00
User opened query 'Per source, subject was dosed at 12:13. Please review and reconcile.' (Site from CRA).		07 Apr 2021 20:41:53
User entered '11:57'		31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '04 Mar 2021 12:13'	System	09 Apr 2021 16:32:22
User entered '04 Mar 2021 11:57'	System	31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:00
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
DataPoint Verified.		07 Apr 2021 20:42:00
User entered 'ONCE'	System	31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'INTRAMUSCULAR'	System	31 Mar 2021 15:36:39

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:42:18
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 15:31:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 15:31:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:31:43
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:27:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:55
User entered 'Yes (Y)'		25 Mar 2021 15:23:44

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:18
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:31:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 15:27:55
User entered '22 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:23:44

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:18
User entered '12:11' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:31:43
User entered empty; reason for change Data Entry Error		25 Mar 2021 15:27:55
User entered '16:02'		25 Mar 2021 15:23:44

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '04 Mar 2021 12:11'	System	31 Mar 2021 15:31:43
User entered empty.	System	25 Mar 2021 15:27:55
User entered '22 Mar 2021 16:02'	System	25 Mar 2021 15:23:44

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:31:25
User entered 'No (N)'		25 Mar 2021 15:24:46

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:24
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:31:25
User entered empty.		25 Mar 2021 15:24:46

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:25

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:24
User entered '12:05' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:31:25
User entered empty.		25 Mar 2021 15:24:46

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:25

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered '04 Mar 2021 12:05'	System	31 Mar 2021 15:31:25
User entered empty.	System	25 Mar 2021 15:24:46

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 15:36:44

US3052295

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:04:53
User entered 'I'	System	31 Mar 2021 15:36:44

US3052295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:14:23

US3052295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:14:23

US3052295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:14:23

US3052295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:14:23

US3052295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:14:27

US3052295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:14:27

US3052295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:14:27
DataPoint set to visible.	System	12 Apr 2021 15:14:27

US3052295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:58

US3052295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:58

US3052295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:58

US3052295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	12 Apr 2021 15:16:58

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '08:55'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 08:55'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '98.1' F	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '77'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '126'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '90'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '10:29'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:29'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '98.3' F	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '76'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '124'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
	(b) (4)	
User entered '86'	(b) (4), (b) (6)	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 15:38:09

US3052295

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:30

US3052295

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:30

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	12 Apr 2021 15:38:51
DataPoint set to visible.	System	12 Apr 2021 15:14:27

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered '09:56'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:56'	System	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Apr 2021 15:38:51

US3052295

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:39:00

US3052295

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:39:00

US3052295

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:57:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	05 Nov 2020 20:01:22
User entered 'Yes (Y)'	Nicole Davis (b) (4)	30 Sep 2020 16:48:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	05 Nov 2020 20:14:40
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:33
User entered	System	01 Oct 2020 16:37:11
'USA-US117-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	01 Oct 2020 16:37:11

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:14:40
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 18:31:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 18:31:58
User closed query 'PV Query: Since discharge diagnosis was syncope please consider updating event term accordingly' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 15:02:28
User closed query 'PV Query: Please update the event term to a single term (i.e. Seizure like activity) and remove additional text. The event term field should not be used to capture any additional information.' (Site from Safety).		03 Nov 2020 15:02:17
Data point term sent to Coder	System	02 Nov 2020 15:56:11
Query 'PV Query: Please update the event term to a single term (i.e. Seizure like activity) and remove additional text. The event term field should not be used to capture any additional information.' answered with 'updated' (Site from Safety).	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:55:43
Query 'PV Query: Since discharge diagnosis was syncope please consider updating event term accordingly' answered with 'updated' (Site from Safety).	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:55:38
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate condition/diagnosis, e.g. SEIZURE / NEUROLOGIC SYMPTOMS / Syncope convulsive etc.' (Site from System).	System	02 Nov 2020 15:55:33
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate condition/diagnosis, e.g. SEIZURE / NEUROLOGIC SYMPTOMS / Syncope convulsive etc.' answered with 'updated' (Site from System).	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:55:33
User entered 'SYNCOPE' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 15:55:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Since discharge diagnosis was syncope please consider updating event term accordingly' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:34:28
User opened query 'PV Query: Please update the event term to a single term (i.e. Seizure like activity) and remove additional text. The event term field should not be used to capture any additional information.' (Site from Safety).		09 Oct 2020 17:07:55
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate condition/diagnosis, e.g. SEIZURE / NEUROLOGIC SYMPTOMS / Syncope convulsive etc. ' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 09:58:17
Data point term sent to Coder	System	30 Sep 2020 17:40:29
User entered 'Seizure like activity with some transient neurologic symptoms. Was admitted for thorough workup with normal (negative) MRI, EEG, Echo. Neurologist DDx: convulsive syncope, seizure, pseudoseizure. '	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '24 Sep 2020'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '14:08'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:08'	System	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User closed query 'Per DM CLR: RQ: Please review the duration of this AE. It is unusual for Syncope to last for more than one day. Effects may last for more than a day but not this event itself. Record any effects of Syncope if there were any. Otherwise, clarify the duration of this event.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 11:53:36
Query 'Per DM CLR: RQ: Please review the duration of this AE. It is unusual for Syncope to last for more than one day. Effects may last for more than a day but not this event itself. Record any effects of Syncope if there were any. Otherwise, clarify the duration of this event.' answered with 'Data is correct' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	31 Dec 2020 21:49:51
User opened query 'Per DM CLR: RQ: Please review the duration of this AE. It is unusual for Syncope to last for more than one day. Effects may last for more than a day but not this event itself. Record any effects of Syncope if there were any. Otherwise, clarify the duration of this event.' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 11:32:34
User closed query 'Per DM CLR: Please review the dates of this AE as it is not expected for an episode of syncope to have a duration of more than 1 day. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:04:25
Query 'Per DM CLR: Please review the dates of this AE as it is not expected for an episode of syncope to have a duration of more than 1 day. Please review and update as appropriate or provide clarification.' answered with 'please review and update' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	23 Nov 2020 13:57:49
DataPoint Un-verified.	Stacey Saldua (b) (4) (b) (4)	23 Nov 2020 13:57:31
User entered '25 Sep 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	23 Nov 2020 13:57:31

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dates of this AE as it is not expected for an episode of syncope to have a duration of more than 1 day. Please review and update as appropriate or provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:11:28
	(b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '26 Sep 2020'	Nicole Davis (b) (4)	30 Sep 2020 17:39:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '10:18'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 10:18'	System	23 Nov 2020 13:57:31
User entered '26 Sep 2020 10:18'	System	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'I'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '24 Sep 2020'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
Query 'Per source, subject was discharged on 27 Sep 2020. Please reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:15:29
DataPoint Un-verified.		05 Nov 2020 20:15:26
DataPoint Verified.		05 Nov 2020 20:14:47
User opened query 'Per source, subject was discharged on 27 Sep 2020. Please reconcile.' (Site from CRA).		05 Nov 2020 20:14:40
User entered '26 Sep 2020'	Nicole Davis (b) (4)	05 Nov 2020 20:07:21
	(b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'Not Related (NOT RELATED)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'Not Related (NOT RELATED)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:14:40
User closed query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with from none to not applicable.' (Site from Safety).		03 Nov 2020 15:02:51
Query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with from none to not applicable.' answered with 'updated' (Site from Safety).	Avia McClain-Stocker	02 Nov 2020 15:55:56
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 15:55:16
	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:08:15
User entered 'None (NONE)'	Nicole Davis (b) (4)	30 Sep 2020 17:39:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
Signature has been broken.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:22:44
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User closed query 'Per DM CLR: Please verify if there were treatments given for this AE as it was noted to require hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify why no treatment was needed.' (Site from DM).		03 Nov 2020 15:43:23
Query 'Per DM CLR: Please verify if there were treatments given for this AE as it was noted to require hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify why no treatment was needed.' answered with 'subject was discharged in stable condition. No medication was needed' (Site from DM).	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:00:08
User opened query 'Per DM CLR: Please verify if there were treatments given for this AE as it was noted to require hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 00:49:37
User entered '1'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4)	30 Sep 2020 17:39:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered '0'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User closed query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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. IF unable to obtain, please state so in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:58:59
Query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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. IF unable to obtain, please state so in your response.' answered with 'Patient did not seek any treatment afterwards ' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	12 Feb 2021 19:20:33
User opened query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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. IF unable to obtain, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 21:10:59
User closed query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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).		29 Jan 2021 20:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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 'As of this time patient has not received any further evaluations. Will follow up with patient to clarify. left patient a message 28 Jan 2021, to call clinic back. ' (Site from Safety).	Stacey Saldua (b) (4)	28 Jan 2021 18:51:29
User opened query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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)	05 Jan 2021 14:38:25
User closed query 'PV Query: Was a test of SARS-CoV-2 performed during the hospitalization? If so, please provide the results. ' (Site from Safety).		04 Jan 2021 17:47:15
User closed query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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).		04 Jan 2021 17:47:10
Query 'PV Query: Was a test of SARS-CoV-2 performed during the hospitalization? If so, please provide the results. ' answered with 'no test was performed ' (Site from Safety).	Stacey Saldua (b) (4)	31 Dec 2020 21:53:15

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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 'Will request records' (Site from Safety).	Stacey Saldua (b) (4)	31 Dec 2020 21:52:38
User opened query 'PV Query: Was a test of SARS-CoV-2 performed during the hospitalization? If so, please provide the results.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:46:28
User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:29:46
Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3.' answered with 'confirmed. please review and update' (Site from Safety).	Stacey Saldua (b) (4)	23 Nov 2020 14:13:01
User opened query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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)	20 Nov 2020 15:30:53
User closed query 'PV Query: Please provide indication, start date, dose, route and frequency of CM. Please add Allegra, Flonase and Sertraline to CM eCRF.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:45:43
User closed query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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)	11 Nov 2020 20:45:38
User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:49:01

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide indication, start date, dose, route and frequency of CM. Please add Allegra, Flonase and Sertraline to CM eCRF.' answered with 'done' (Site from Safety).	Stacey Saldua (b) (4)	10 Nov 2020 19:51:45
Query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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 'Patient was seen at Heart and Vascular Center for follow up. Medical records will be sent.' (Site from Safety).	Stacey Saldua (b) (4)	10 Nov 2020 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:14:40
User closed query 'Per DM CLR: SAE Narrative indicates that MRI, EEG and ECHO was performed. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).		03 Nov 2020 15:44:11
User closed query 'PV Query: Please add treatment medication, Keppra, to CM eCRF.' (Site from Safety).		03 Nov 2020 15:03:07
User closed query 'PV Query Urgent: Please add subject's medical history to medical history eCRF.' (Site from Safety).		03 Nov 2020 15:03:03
Query 'Per DM CLR: SAE Narrative indicates that MRI, EEG and ECHO was performed. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'updated Concomitant Procedures' (Site from DM).	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:43:08
Query 'PV Query: Please add treatment medication, Keppra, to CM eCRF.' answered with 'added' (Site from Safety).	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:20
Query 'PV Query Urgent: Please add subject's medical history to medical history eCRF.' answered with 'updated' (Site from Safety).	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:02:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative indicates that MRI, EEG and ECHO was performed. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 00:50:14
User opened query 'PV Query: Please add treatment medication, Keppra, to CM eCRF.' (Site from Safety).		23 Oct 2020 13:32:09
User opened query 'PV Query: Please provide indication, start date, dose, route and frequency of CM. Please add Allegra, Flonase and Sertraline to CM eCRF.' (Site from Safety).		23 Oct 2020 13:29:44
Query 'PV Query Urgent: Please send a hospital discharge summary including all diagnostic, laboratory, and physical exams with results 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.' canceled (Site from Safety).		21 Oct 2020 12:27:56
Query 'PV Query Urgent: Please provide details, with dates, of any treatments for the event, including medical or surgical procedures.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:39:06
Query 'PV Query Urgent: Please add concomitant and treatment medications to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' canceled (Site from Safety).		12 Oct 2020 16:39:04
User opened query 'PV Query: Did the subject receive any outpatient follow-up evaluations or treatment after hospital discharge? If so, please send outpatient records 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).		09 Oct 2020 17:10:32
User opened query 'PV Query Urgent: Please provide details, with dates, of any treatments for the event, including medical or surgical procedures.' (Site from Safety).		09 Oct 2020 17:10:17

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query Urgent: Please add concomitant and treatment medications to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:10:07
User opened query 'PV Query Urgent: Please send a hospital discharge summary including all diagnostic, laboratory, and physical exams with results 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).		09 Oct 2020 17:09:53
User opened query 'PV Query Urgent: Please add subject's medical history to medical history eCRF.' (Site from Safety).		09 Oct 2020 17:09:34
Query 'PV Query Urgent: Please provide the clinical summary of the event including a timeline of when events occurred.' canceled (Site from Safety).		09 Oct 2020 17:09:19
Query 'PV Query Urgent: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' canceled (Site from Safety).		09 Oct 2020 17:09:16
Query 'PV Query Urgent: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' canceled (Site from Safety).		09 Oct 2020 17:09:12
Query 'PV Query Urgent: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).		09 Oct 2020 17:09:10
Query 'PV Query Urgent: Please confirm is the subject has a history of similar events (i.e. syncope)? canceled (Site from Safety).		09 Oct 2020 17:09:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query Urgent: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:09:04
Query 'PV Query Urgent: 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.' canceled (Site from Safety).		09 Oct 2020 17:09:01
Query 'PV Query Urgent: Did the subject have an ECG? Please provide results, if applicable. ' canceled (Site from Safety).		09 Oct 2020 17:08:58
Query 'PV Query Urgent: Please confirm the MRI is for the brain. Additionally, please confirm the echo was cardiac. ' canceled (Site from Safety).		09 Oct 2020 17:08:55
Query 'PV Query Urgent: Are there documented blood pressure readings prior to or during the event?' canceled (Site from Safety).		09 Oct 2020 17:08:51
Query 'PV Query Urgent: In what circumstances did the syncope happened? E.g. exposure to heat, prolonged standing period, exercise, emotional trigger?' canceled (Site from Safety).		09 Oct 2020 17:08:48
Query 'PV Query Urgent: Please confirm this event occurred the day following the subject's second dose of study drug.' canceled (Site from Safety).		09 Oct 2020 17:08:43
User opened query 'PV Query Urgent: Please provide the clinical summary of the event including a timeline of when events occurred. ' (Site from Safety).		02 Oct 2020 14:38:35
User opened query 'PV Query Urgent: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).		02 Oct 2020 14:38:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query Urgent: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:38:17
User opened query 'PV Query Urgent: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		02 Oct 2020 14:38:07
User opened query 'PV Query Urgent: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		02 Oct 2020 14:37:57
User opened query 'PV Query Urgent: Please confirm is the subject has a history of similar events (i.e. syncope)?' (Site from Safety).		02 Oct 2020 14:37:48
User opened query 'PV Query Urgent: 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).		02 Oct 2020 14:37:39
User opened query 'PV Query Urgent: Did the subject have an ECG? Please provide results, if applicable.' (Site from Safety).		02 Oct 2020 14:37:29
User opened query 'PV Query Urgent: Please confirm the MRI is for the brain. Additionally, please confirm the echo was cardiac.' (Site from Safety).		02 Oct 2020 14:37:19
User opened query 'PV Query Urgent: Are there documented blood pressure readings prior to or during the event?' (Site from Safety).		02 Oct 2020 14:37:08
User opened query 'PV Query Urgent: In what circumstances did the syncope happened? E.g. exposure to heat, prolonged standing period, exercise emotional trigger?' (Site from Safety).		02 Oct 2020 14:36:30
User opened query 'PV Query Urgent: Please confirm this event occurred the day following the subject's second dose of study drug.' (Site from Safety).		02 Oct 2020 14:36:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Seizure like activity with some transient neurologic symptoms. Was admitted for thorough workup with normal (negative) MRI, EEG, Echo. Neurologist DDx: convulsive syncope, seizure, pseudoseizure. Discharged home after a negative workup. Patient at baseline with no residual on discharge.'	Nicole Davis (b) (4) (b) (4)	30 Sep 2020 17:39:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 17:39:44

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 13:24:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 13:24:34
Data point term sent to Coder	System	01 Apr 2021 13:23:56
User entered 'constipation'	(b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Apr 2021 13:23:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 13:23:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:23:32
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 15:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 15:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
User entered empty.	System	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
User entered empty.	System	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

US3052295

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 15:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 15:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 15:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	05 Apr 2021 15:00:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Apr 2021 13:23:23
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 15:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	05 Apr 2021 15:00:03
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:23:23
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:26
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
User entered '0'	System	01 Apr 2021 13:23:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58
User entered '0'	System	01 Apr 2021 13:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:57:25

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:43
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 19:51:50
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, 4, 6 Headache, Day 4, 6 Nausea/Vomiting, Day 4 Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 10:25:24
Query 'Per DM CLR: Per Diary Dose 2 Day 2, 4, 6 Headache, Day 4, 6 Nausea/Vomiting, Day 4 Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'discussed symptoms but did not indicate having taken medication ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:07:06
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, 4, 6 Headache, Day 4, 6 Nausea/Vomiting, Day 4 Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:59:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:19:58
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:04:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:57:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:57:17
Data point term sent to Coder	System	02 Nov 2020 16:31:04
Coding entries removed.	Avia McClain-Stocker	02 Nov 2020 16:30:37
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 12:49:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 12:49:22
Data point term sent to Coder	System	31 Oct 2020 12:36:11
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	31 Oct 2020 12:35:12
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	31 Oct 2020 11:31:09
' (Site from System).		

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Oct 2020 13:08:32
User entered 'Zyrtec'	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
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) (4), (b) (6)	02 Feb 2021 12:00:01
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 'updated' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:00:31
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).	(b) (4), (b) (6)	17 Dec 2020 09:05:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'seasonal allergies' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:30:37
User entered 'Unknown'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '1' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 16:00:53
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:30:37
	(b) (4)	
User entered 'UNKNOWN'	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 16:00:53
User entered 'mg (mg)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:30:37
User entered 'Other (OTHER)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:30:37
	(b) (4)	
User entered 'Unknown'	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'once daily (QD)'	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'UN UNK 2000' reason for change:	Avia McClain-Stocker	11 Nov 2020 16:00:53
Data Entry Error	(b) (4)	
User entered 'UN UNK 2018' reason for change:	Avia McClain-Stocker	02 Nov 2020 16:30:37
Data Entry Error	(b) (4)	
User entered 'UN UNK 2000'	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:08:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 23:07:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Nov 2020 23:07:17
Data point term sent to Coder	System	02 Nov 2020 16:33:11
Coding entries removed.	Avia McClain-Stocker	02 Nov 2020 16:32:22
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:44:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	30 Oct 2020 03:44:15
Data point term sent to Coder	System	29 Oct 2020 13:11:39
User entered 'Allegra'	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'seasonal allergies' reason for change:	Avia McClain-Stocker	02 Nov 2020 16:32:22
Data Entry Error	(b) (4)	
User entered 'Unknown'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:17
User closed query 'Please review source and confirm dose matches.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:21:14
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Please review source and confirm dose matches.' answered with 'confirmed' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:09:32
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:01:53
User opened query 'Please review source and confirm dose matches.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:01:51
DataPoint Verified.		07 Apr 2021 20:01:04
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.		02 Feb 2021 12:00:44
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Stacey Saldua (b) (4)	28 Jan 2021 19:14:24
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Stacey Saldua (b) (4)	28 Jan 2021 19:14:04
User entered '180' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Stacey Saldua (b) (4)	28 Jan 2021 19:14:04
' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 09:05:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Unknown'	(b) (4), (b) (6)	
	Avia McClain-Stocker (b) (4)	11 Nov 2020 18:37:12
	(b) (4)	
	Stacey Saldua (b) (4)	11 Nov 2020 16:01:11
	(b) (4)	
	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:01:04
DataPoint Un-verified.	Stacey Saldua (b) (4)	28 Jan 2021 19:14:04
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	28 Jan 2021 19:14:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'tablet (TABLET)'	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'once daily (QD)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'UN UNK 2000'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:11:02
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 13:11:02

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 23:07:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Nov 2020 23:07:14
Data point term sent to Coder	System	02 Nov 2020 16:33:11
Data point term sent to Coder	System	02 Nov 2020 16:32:10
Coding entries removed.	Avia McClain-Stocker	02 Nov 2020 16:32:09
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:46:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:46:10
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 13:15:48
User entered 'Flonase'	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
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) (4), (b) (6)	02 Feb 2021 12:01:00
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 'updated' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:16:29
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).	(b) (4), (b) (6)	17 Dec 2020 09:05:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:32:33
User entered 'allergies' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:32:09
User entered 'Unknown'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '1' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 16:01:39
	(b) (4)	
User entered 'Unknown'	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'puff (PUFF)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'as needed (PRN)' reason for change:	Avia McClain-Stocker	11 Nov 2020 16:01:39
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	11 Nov 2020 16:01:39
	(b) (4)	
User entered 'As needed'	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Nasal (NASAL)'	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'UN UNK 2000'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:15:22
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 13:15:22

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 23:02:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 23:02:07
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 16:32:10
Coding entries removed.	Avia McClain-Stocker	02 Nov 2020 16:31:43
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 16:43:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 16:43:50
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 13:17:51
User entered 'Sertraline'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 09:05:33
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 09:05:29
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'anxiety' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:31:43
User entered 'Unknown'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '200' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:31:43
	(b) (4)	
User entered '20'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'mg (mg)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'as needed (PRN)' reason for change:	Avia McClain-Stocker	11 Nov 2020 16:02:08
Data Entry Error	(b) (4)	
User entered 'once daily (QD)' reason for change:	Avia McClain-Stocker	02 Nov 2020 16:31:43
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:31:43
	(b) (4)	
User entered 'As needed'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Oral (ORAL)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'UN UNK 2010' reason for change:	Avia McClain-Stocker	11 Nov 2020 16:02:08
Data Entry Error	(b) (4)	
User entered 'UN UNK 2018' reason for change:	Avia McClain-Stocker	02 Nov 2020 16:31:43
Data Entry Error	(b) (4)	
User entered 'UN UNK 2010'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Stacey Saldua (b) (4)	29 Oct 2020 13:17:25
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:02:08
User entered '1'	System	02 Nov 2020 16:31:43
User entered empty.	System	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:02:08
User entered '1'	System	02 Nov 2020 16:31:43
User entered empty.	System	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:02:08
User entered '804 (804)'	System	02 Nov 2020 16:31:43
User entered empty.	System	29 Oct 2020 13:17:25

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 22:00:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 22:00:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
Data point term sent to Coder	System	11 Nov 2020 15:53:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'enoxaparin' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
Data point term sent to Coder	System	11 Nov 2020 15:39:02
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:53:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:53:57
Data point term sent to Coder	System	02 Nov 2020 16:21:54
User entered 'keppra'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:04:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Event does not qualify as an AE. Subject given medication as routine preventative measures per doctor's orders to keep from getting blood clots.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 21:03:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 09:05:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'deep vein thrombosis prevention' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'seizures'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered '40' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'unknown'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'mg (mg)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'Other (OTHER)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'unknown'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'once daily (QD)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'unknown (UNKNOWN)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'Other (OTHER)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'unknown'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Nov 2020 15:52:53
User entered '25 Sep 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered '25 Sep 2020'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered '25 Sep 2020'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:52:53
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 15:38:05
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:38:05
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User entered '1'	System	11 Nov 2020 15:52:53
User entered empty.	System	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User entered '1'	System	11 Nov 2020 15:52:53
User entered empty.	System	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:13
User entered '804 (804)'	System	11 Nov 2020 15:52:53
User entered empty.	System	02 Nov 2020 16:21:18

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
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)	11 Nov 2020 15:50:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 15:50:33
	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 15:49:13
Coding entries removed.	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
Coding entries removed.	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
User entered 'Aspirin' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 00:21:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 00:21:43
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 16:29:02
Data point term sent to Coder	System	02 Nov 2020 16:22:55
User entered 'lovenox'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:22:42

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'health maintenance' reason for change:	Avia McClain-Stocker	11 Nov 2020 15:48:46
Data Entry Error	(b) (4)	
User entered 'deep vein thrombosis'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '81' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
User entered '40' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:28:07
	(b) (4)	
User entered 'unknown'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'mg (mg)' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:28:07
	(b) (4)	
User entered 'Other (OTHER)'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:28:07
	(b) (4)	
User entered 'unknown'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'once daily (QD)' reason for change:	Avia McClain-Stocker	11 Nov 2020 15:48:46
Data Entry Error	(b) (4)	
User entered 'once (ONCE)' reason for change: Data	Avia McClain-Stocker	02 Nov 2020 16:28:07
Entry Error	(b) (4)	
User entered 'unknown (UNKNOWN)'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:22:42

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:28:07
	(b) (4)	
User entered 'Other (OTHER)'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	02 Nov 2020 16:28:07
	(b) (4)	
User entered 'unknown'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'un UNK 2020' reason for change:	Avia McClain-Stocker	11 Nov 2020 15:48:46
Data Entry Error	(b) (4)	
User entered '24 Sep 2020'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 15:48:52
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:48:52
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 15:48:46
User entered '24 ' (non-conformant).	Avia McClain-Stocker	11 Nov 2020 15:48:46
	(b) (4)	
User entered '24 Sep 2020'	Avia McClain-Stocker	02 Nov 2020 16:22:42
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 16:22:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 16:22:49
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:22:49
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 16:22:42
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:22:42

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 15:48:46
User entered empty.	System	02 Nov 2020 16:22:42

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 15:48:46
User entered empty.	System	02 Nov 2020 16:22:42

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 15:48:46
User entered empty.	System	02 Nov 2020 16:22:42

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
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.	Coder Import (b) (4)	04 Nov 2020 23:17:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 23:17:11
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 16:34:13
User entered 'atorvastatin'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:20
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:22:16
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 09:05:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'high cholesterol'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '20' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:49:40
	(b) (4)	
User entered 'unknown'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'mg (mg)' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:49:40
	(b) (4)	
User entered 'Other (OTHER)'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:49:40
	(b) (4)	
User entered 'unknown'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'once daily (QD)' reason for change:	Avia McClain-Stocker	11 Nov 2020 15:49:40
Data Entry Error	(b) (4)	
User entered 'unknown (UNKNOWN)'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Oral (ORAL)'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'un UNK 2020' reason for change:	Avia McClain-Stocker	11 Nov 2020 15:49:40
Data Entry Error	(b) (4)	
User entered empty.	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0' reason for change: Data Entry Error	Avia McClain-Stocker	11 Nov 2020 15:49:40
	(b) (4)	
User entered '1'	Avia McClain-Stocker	02 Nov 2020 16:34:06
	(b) (4)	

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 15:49:40
User entered empty.	System	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 15:49:40
User entered empty.	System	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 15:49:40
User entered empty.	System	02 Nov 2020 16:34:06

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:52:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:52:33
Data point term sent to Coder	System	11 Nov 2020 15:51:18
Coding entries removed.	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:50:39
User entered 'senokot' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:50:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:26:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:26:02
Data point term sent to Coder	System	02 Nov 2020 16:35:14
User entered 'sennosides-docusate sodium'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
User closed query 'Per CDM CLR re-query: Response noted; however no update made on AE eCRF. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:33:56
Query 'Per CDM CLR re-query: Response noted; however no update made on AE eCRF. Kindly review and update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:21:23
User opened query 'Per CDM CLR re-query: Response noted; however no update made on AE eCRF. Kindly review and update accordingly. Thank you.' (Site from DM).		02 Feb 2021 18:47:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'		02 Feb 2021 18:46:17
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	Stacey Saldua (b) (4)	28 Jan 2021 19:29:35
' answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	17 Dec 2020 09:05:55
' (Site from DM).		
DataPoint Verified.		11 Nov 2020 18:37:12
User entered 'constipation'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '2'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'tablet (TABLET)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'once daily (QD)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'Oral (ORAL)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered empty.	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '25 Sep 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:50:39
User entered '24 Sep 2020'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '0'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	11 Nov 2020 15:50:39
User entered '25 Sep 2020'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 18:59:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:37:12
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User entered '1'	System	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User entered '1'	System	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:34:18
User entered '804 (804)'	System	02 Nov 2020 16:35:01

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:57:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:43
Query 'Please review source and make sure terms match what is recorded in EDC. Update source accordingly.' canceled (Site from CRA).		09 Apr 2021 16:19:24
User opened query 'Please review source and make sure terms match what is recorded in EDC. Update source accordingly.' (Site from CRA).		07 Apr 2021 20:03:12
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:02:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Yes (Y)'	(b) (4)	
	Avia McClain-Stocker	02 Nov 2020 16:35:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '25 Sep 2020'	Avia McClain-Stocker	02 Nov 2020 16:37:52

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '2D Echocardiogram'	Avia McClain-Stocker (b) (4)	02 Nov 2020 16:37:52

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Adverse Event (AE)'	Avia McClain-Stocker	02 Nov 2020 16:37:52
	(b) (4)	

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:25

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered empty.	(b) (4) Avia McClain-Stocker	02 Nov 2020 16:37:52
	(b) (4)	

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '24 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:39:45

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'CT Scan'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:39:45

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Adverse Event (AE)'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:39:45

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:39:45

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '24 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:13

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'MRI'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:13

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Adverse Event (AE)'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:13

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:13

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '24 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:34

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'EEG'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:34

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Adverse Event (AE)'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:34

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:40:34

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '24 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:41:24

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Transthoracic echo'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:41:24

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Adverse Event (AE)'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:41:24

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:41:24

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '24 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:42:42

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Ultrasound Carotid Doppler Bilateral'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:42:42

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'Adverse Event (AE)'	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:42:42

US3052295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:19:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	02 Nov 2020 16:42:42

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.		01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.		16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'Fayetteville'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change:		16 Apr 2021 17:02:04
Data Entry Error		
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.		16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'Fayetteville'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change:		16 Apr 2021 17:02:04
Data Entry Error		
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:05:13
User entered '01/Oct/2020 12:37'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.		03 Nov 2020 15:05:28
User entered 'I'		01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
DataPoint Un-verified.		
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	System	11 Nov 2020 20:46:50
User entered 'Fayetteville' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 20:46:04
Un-reviewed for Safety.		11 Nov 2020 16:05:13
User entered empty.	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
Reviewed for Safety.	(b) (4)	
DataPoint Verified.	System	03 Nov 2020 15:05:42
User entered 'Fayetteville' reason for change: Data Entry Error	System	03 Nov 2020 15:05:42
User signature succeeded.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
Reviewed for Safety.		
User entered 'Fayetteville' reason for change: Data Entry Error	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
User signature succeeded.	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change:		16 Apr 2021 17:02:04
Data Entry Error		
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
DataPoint Un-verified.		
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
	System	11 Nov 2020 20:46:50
	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information		
Un-reviewed for Safety.	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
User entered empty.	(b) (4)	
Reviewed for Safety.	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:42
	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'		
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:05:13
User entered '03/Nov/2020 15:05'	System	03 Nov 2020 15:05:42

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:13
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 15:05:42

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.		16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'Fayetteville'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	(b) (4), (b) (6) 12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	System	03 Nov 2020 15:05:42
	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '11/Nov/2020 20:46'	(b) (4) System	11 Nov 2020 20:46:50

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:46:50

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.		16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'Fayetteville'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change:		16 Apr 2021 17:02:04
Data Entry Error		
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.		03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '12/Nov/2020 21:15'	(b) (4) System	12 Nov 2020 21:15:16

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:30:03
User entered 'I'		12 Nov 2020 21:15:16

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.		16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'Fayetteville'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change:		16 Apr 2021 17:02:04
Data Entry Error		
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	Svstem	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '24/Nov/2020 19:30'	(b) (4) System	24 Nov 2020 19:30:16

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:59:20
User entered 'I'		24 Nov 2020 19:30:16

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'USA-US117-2020-MRNA-1273-P301000002'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Yes (Y)'	System	01 Oct 2020 16:37:11

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'No (N)'	System	01 Oct 2020 16:37:11

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Judith'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:37:48
User entered 'Borger'	System	01 Oct 2020 16:37:11

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	16 Apr 2021 17:20:37
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:02:04
DataPoint Un-verified.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '1565 Purdue Drive, Suite 101' reason for change: Data Entry Error		16 Apr 2021 17:02:04
DataPoint Verified.		16 Apr 2021 15:12:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	(b) (4), (b) (6)	
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
User closed query 'Please update Site address fields.' (Site from CRA).		11 Nov 2020 16:05:13
Query 'Please update Site address fields.' answered with 'done' (Site from CRA).		11 Nov 2020 16:05:06
User entered '1565 Purdue Drive Suite 101' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:27
User opened query 'Please update Site address fields.' (Site from CRA).	(b) (4)	11 Nov 2020 15:23:16
Un-reviewed for Safety.	Stacey Saldua (b) (4)	05 Nov 2020 20:19:07
User entered empty.	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:42
User entered '1565 Purdue Drive'	System	03 Nov 2020 15:05:42
	System	03 Nov 2020 15:05:28
	(b) (4), (b) (6)	
	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'Fayetteville' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'Fayetteville' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'Fayetteville'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered 'North Carolina' reason for change:		16 Apr 2021 17:02:04
Data Entry Error		
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered 'NC' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'NC'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

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Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:20:37
Un-reviewed for Safety.		16 Apr 2021 17:02:04
Signature has been broken.		16 Apr 2021 17:02:04
User entered '28303' reason for change: Data Entry Error		16 Apr 2021 17:02:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:15:07
Un-reviewed for Safety.	System	11 Nov 2020 20:46:50
DataPoint Un-verified.	System	11 Nov 2020 20:46:50
User entered empty.	System	11 Nov 2020 20:46:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:46:04
DataPoint Verified.		11 Nov 2020 16:05:13
User entered '28303' reason for change: New Information	Stacey Saldua (b) (4)	11 Nov 2020 15:23:16
	(b) (4)	
Un-reviewed for Safety.	System	03 Nov 2020 15:05:42
User entered empty.	System	03 Nov 2020 15:05:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered '28303'	Stacey Saldua (b) (4)	20 Oct 2020 21:44:55
	(b) (4)	

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:05:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:05:28
User entered 'US'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Feb 2021 15:59:48
User entered '5'	System	24 Nov 2020 19:30:16
User entered '4'	System	12 Nov 2020 21:15:16
User entered '3'	System	11 Nov 2020 20:46:50
User entered '2'	System	03 Nov 2020 15:05:42
User entered '1'	System	01 Oct 2020 16:37:54

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered '16/Feb/2021 09:59'	(b) (4) System	16 Feb 2021 15:59:48

US3052295

Folder: SAE USA-US117-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:57
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 15:59:48