

US3052315 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:59:24

All time stamps listed in this document are displayed in GMT

US3052315

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 16:53:49

Generated On: 09 Jun 2021 14:59:24

[Participant ID](#)

US3052315

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

US3052315

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 28 AUG 2020

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

Folder OID SCRN

US3052315

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3052315

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Date of Informed Consent (*dd MMM yyyy*) 28 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3052315

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Did the participant meet all eligibility criteria?

Yes

No

US3052315

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Condition	HERNIATED DISC IN NECK
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Condition	DISC FUSION IN NECK
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Condition	CONGENITAL ATRIAL SEPTAL DEFECT
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Condition	SHOULDER SURGERY (RIGHT)- ROTATOR CUFF
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:56 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:56
Height (<i>xxx.x</i>)	186 cm
Weight (<i>xxx.x</i>)	109.09 kg
BMI (<i>xxx.x</i>)	31.53255 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

28 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: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 16:54:08

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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 RETIRED

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 16:54:08

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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 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 28 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 188849

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 16:54:09

Generated On: 09 Jun 2021 14:59:24

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 16:54:09

Generated On: 09 Jun 2021 14:59:24

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 (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:56 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:56
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 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 16:54:09

Generated On: 09 Jun 2021 14:59:24

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 (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:26 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:26
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 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 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 11:48 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 11:48

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 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 AUG 2020

Collection time (*00:00-23:59*) 11:35 (24 HR)

Collection date and time (derived) 28 AUG 2020 11:35

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Collection date (<i>dd MMM yyyy</i>)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:44	28 AUG 2020 11:44
Nasopharyngeal Swab 2	No		

US3052315

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:54:08

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 28 AUG 2020 12:08

PC Close Date & Time 28 AUG 2020 14:38

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp	28 AUG 2020 16:56
PC Open Date & Time	28 AUG 2020 15:33
PC Close Date & Time	29 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 AUG 2020 20:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

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 98.3 °F

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

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

PC Time Stamp 01 SEP 2020 06:33

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 07:21
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 12:00
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

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

PC Time Stamp	03 SEP 2020 12:51
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:08

PC Close Date & Time

28 AUG 2020 14:38

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

28 AUG 2020 16:57

PC Open Date & Time

28 AUG 2020 15:33

PC Close Date & Time

29 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 2

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

29 AUG 2020 20:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 3

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	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 4

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

01 SEP 2020 06:33

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 5

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	02 SEP 2020 07:22
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 6

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

02 SEP 2020 12:00

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

03 SEP 2020 12:52

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

No

Yes

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:08

PC Close Date & Time

28 AUG 2020 14:38

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

No
Yes

PC Time stamp	28 AUG 2020 16:58
PC Open Date & Time	28 AUG 2020 15:33
PC Close Date & Time	29 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 20:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

Yes

PC Time stamp	30 AUG 2020 12:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 06:34
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 07:22
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 12:02
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 12:52
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3052315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 SEP 2020

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

Folder OID VISIT2

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

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 (<i>dd MMM yyyy</i>)	25 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:18 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:18
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

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 (<i>dd MMM yyyy</i>)	25 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:49 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:49
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3052315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 11:19 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 11:19

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

US3052315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 SEP 2020

Collection time (*00:00-23:59*) 11:14 (24 HR)

Collection date and time (derived) 25 SEP 2020 11:14

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Collection date (<i>dd MMM yyyy</i>)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	25 SEP 2020 11:17
Nasopharyngeal Swab 2	No		

US3052315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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 25 SEP 2020 11:52

PC Open Date & Time 25 SEP 2020 11:39

PC Close Date & Time 25 SEP 2020 14:09

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.4 °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 SEP 2020 09:54
PC Open Date & Time 25 SEP 2020 15:04
PC Close Date & Time 26 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 SEP 2020 12:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 SEP 2020 12:11
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 SEP 2020 16:14
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 30 SEP 2020 09:36
PC Open Date & Time 29 SEP 2020 12:00
PC Close Date & Time 30 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 SEP 2020 12:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 OCT 2020 17:03
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

25 SEP 2020 11:52

PC Open Date & Time

25 SEP 2020 11:39

PC Close Date & Time

25 SEP 2020 14:09

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

26 SEP 2020 09:55

PC Open Date & Time

25 SEP 2020 15:04

PC Close Date & Time

26 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 2

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	26 SEP 2020 12:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 3

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

27 SEP 2020 12:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 4

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

28 SEP 2020 16:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 5

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

30 SEP 2020 09:36

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 6

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

30 SEP 2020 12:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 7

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

01 OCT 2020 17:03

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

No

Yes

PC Time stamp	25 SEP 2020 11:52
PC Open Date & Time	25 SEP 2020 11:39
PC Close Date & Time	25 SEP 2020 14:09

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

No

Yes

PC Time stamp	26 SEP 2020 09:55
PC Open Date & Time	25 SEP 2020 15:04
PC Close Date & Time	26 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 12:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 12:12
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 16:15
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 09:36
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 12:02
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

	Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 17:04
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3052315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 OCT 2020

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

Folder OID VISIT3

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 10:10
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3052315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3052315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	20 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:23 (24 HR)
Collection date and time (derived)	20 OCT 2020 10:23

US3052315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:54:09

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 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	28 OCT 2020 14:19:08
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 06 NOV 2020 13:59:41

Patient Cloud Open Date & Time 04 NOV 2020 00:01

Patient Cloud Close Date & Time 08 NOV 2020 23:59

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 103

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#) 10 DEC 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 110

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 JAN 2021 10:52:53
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 JAN 2021 02:19:43
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 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	17 JAN 2021 07:15:45
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 24 JAN 2021 19:46:53

Patient Cloud Open Date & Time 24 JAN 2021 00:01

Patient Cloud Close Date & Time 28 JAN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 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	02 FEB 2021 17:20:58
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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	08 FEB 2021 10:09:49
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 16 FEB 2021 12:00:46

Patient Cloud Open Date & Time 14 FEB 2021 00:01

Patient Cloud Close Date & Time 18 FEB 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 08:12:14
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 <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	01 MAR 2021 18:52:46
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 MAR 2021 21:21:20
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 12:30:34
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 21 MAR 2021 09:07:24

Patient Cloud Open Date & Time 21 MAR 2021 00:01

Patient Cloud Close Date & Time 25 MAR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 14:23:36
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 APR 2021 08:08:37
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 08:39:25
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 06:04:02
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 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	25 APR 2021 00:24:47
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 264

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

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	16 MAY 2021 00:01
Patient Cloud Close Date & Time	20 MAY 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 341

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 390

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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
Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 425

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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
Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

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27 JAN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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Date and time of submission	
Patient Cloud Open Date & Time	13 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 24 FEB 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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
Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2022 00:01
Patient Cloud Close Date & Time	02 JUN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 656

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2022 00:01
Patient Cloud Close Date & Time	23 JUN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 719

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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
Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 Yes

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#) 06 OCT 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

[Patient Cloud Close Date & Time](#) 27 OCT 2022 23:59

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2022 00:01
Patient Cloud Close Date & Time	03 NOV 2022 23:59

US3052315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:59:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 18:52:57

US3052315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 16:31:55

Generated On: 09 Jun 2021 14:59:24

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 _____

US3052315

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 DEC 2020

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

Comments LEFT VM

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 16:31:55

Generated On: 09 Jun 2021 14:59:24

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 _____

US3052315

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:36:50

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID VISIT4

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:36:50

Generated On: 09 Jun 2021 14:59:24

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 22 MAR 2021

Time of assessment (00:00-23:59) 11:25 (24 HR)

Vital Signs Date and Time (derived) 22 MAR 2021 11:25

Temperature (xxx.x) 98.9 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 94 beats/min

Pulse units BPM

Respiratory Rate (xxx) 17 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 128 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 84 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3052315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:36:50

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3052315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 12:07 (24 HR)

Collection date and time (derived) 22 MAR 2021 12:07

US3052315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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 _____

US3052315

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

Date of Contact	14 JAN 2021
Time of Contact	11:00
Date and Time of Contact (derived)	14 JAN 2021 11:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	_____
---------------	-------

O2 Saturation Units	_____
---------------------	-------

Temperature	_____
-------------	-------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 30 Apr 2021 19:53:57

Generated On: 09 Jun 2021 14:59:24

Date of Visit 14 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 14 JAN 2021

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Date of Contact	22 DEC 2020
Time of Contact	12:52
Date and Time of Contact (derived)	22 DEC 2020 12:52
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input type="checkbox"/> Safety Call <input checked="" type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 May 2021 23:22:06

Generated On: 09 Jun 2021 14:59:24

Date of Visit 22 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 09 DEC 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed FIRST HEALTH OF THE CAROLINAS

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 03 May 2021 23:22:06

Generated On: 09 Jun 2021 14:59:24

Did the subject have Respiratory Rates \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ \leq 93% on room air at sea level? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio $<$ 300 mm Hg? Yes
No

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date 09 DEC 2020

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes
No

Start Date _____

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 03 May 2021 23:22:06

Generated On: 09 Jun 2021 14:59:24

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes No

Start Date 09 DEC 2020

End Date 18 DEC 2020

Non-Invasive Ventilation? Yes No

Start Date _____

End Date _____

Mechanical Ventilation? Yes No

Start Date _____

End Date _____

ECMO? Yes No

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes No

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes No

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes No

Start Date _____

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 03 May 2021 23:22:06

Generated On: 09 Jun 2021 14:59:24

Hepatic Dysfunction? Yes
No

Start Date _____

Neurologic Dysfunction? Yes
No

Start Date _____

Evidence of Pneumonia:

Clinical Evidence Yes
No

Date of Assessment 09 DEC 2020

Radiographical Evidence Yes
No

Date of Assessment _____

Admission to an intensive care unit due to SARS-CoV-2 Yes
No

Start Date _____

End Date _____

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

[Generate Next COVID-19 Assessment](#)

Yes

No

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3052315

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 13:52:31

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID SICKD1

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 13:52:31

Generated On: 09 Jun 2021 14:59:24

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3052315

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

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.

US3052315

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 23 Apr 2021 13:52:31

Generated On: 09 Jun 2021 14:59:24

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	11:20 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:20
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

14 JAN 2021

US3052315

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 JAN 2021

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

Folder OID UNBLND_DECIDE

US3052315

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Date of updated informed consent (<i>dd MMM yyyy</i>)	27 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3052315

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Apr 2021 02:32:49

Generated On: 09 Jun 2021 14:59:24

Height	182.88 cm
Weight	94.8 kg
BMI (xxx.x)	28.34496

US3052315

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Apr 2021 02:32:49

Generated On: 09 Jun 2021 14:59:24

Height	182.88 cm
Weight	94.8 kg
BMI (xxx.x)	28.34496
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)	27 JAN 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 12:39
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3052315

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Apr 2021 02:32:49

Generated On: 09 Jun 2021 14:59:24

Height	182.88 cm
Weight	94.8 kg
BMI (xxx.x)	28.34496
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)	27 JAN 2021
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 14:57
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3052315

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3052315

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

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) 27 JAN 2021

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 14:20

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

What was the frequency of the study treatment dosing? ONCE

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

US3052315

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 27 JAN 2021

Collection time (*00:00-23:59*) 13:36 (24 HR)

Collection date and time (derived) 27 JAN 2021 13:36

US3052315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 27 JAN 2021

Collection time (*00:00 - 23:59*) 13:38

Collection Date and Time (derived) 27 JAN 2021 13:38

US3052315

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

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

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

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

Comments MISSED

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

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 (<i>dd MMM yyyy</i>)	1 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:30 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 11:30
Temperature (<i>xxx.x</i>)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

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 (<i>dd MMM yyyy</i>)	1 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:38 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 12:38
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3052315

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

1 MAR 2021

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

US3052315

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

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) 1 MAR 2021

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 12:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3052315

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:51

Generated On: 09 Jun 2021 14:59:24

Was Contact Attempted? Yes
No

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

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

Comments MISSED

If Contact Not Made, please provide Comments

US3052315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3052315

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID OLD57

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:25 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 11:25
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3052315

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

22 MAR 2021

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

US3052315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:36:49

Generated On: 09 Jun 2021 14:59:24

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 12:07 (24 HR)

Collection date and time (derived) 22 MAR 2021 12:07

US3052315

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 16:53:49

Generated On: 09 Jun 2021 14:59:24

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3052315

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

AEID	USA-US117-2020-MRNA-1273-P30 1000005
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	27 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	18 DEC 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) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

Number of Days in ICU	
Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

US3052315

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

SUBJECT DEVELOPED SYMPTOMS ON 11/27, TESTED POSITIVE FOR COVID 19 ON 6 DEC 2020 AND WAS HOSPITALIZED DUE TO DISEASE ON 9 DEC 2020, DISCHARGED HOME ON HOME OXYGEN ON 18 DEC 2020. SUBJECT INFORMED SITE OF HOSPITAL ADMISSION AND DIAGNOSIS 12:52 ON 06 DEC 2020.

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

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

AEID USA-US117-2020-MRNA-1273-P30
1000005

Adverse event BILATERAL PNEUMONIA DUE
TO COVID-19

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) 9 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 18 DEC 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 True

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 9 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 18 DEC 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

AEID USA-US117-2020-MRNA-1273-P30
1000005

Adverse event ACUTE RESPIRATORY FAILURE
WITH HYPOXIA

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) 9 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 18 DEC 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 True

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 9 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 18 DEC 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

AEID USA-US117-2020-MRNA-1273-P30
1000005

Adverse event THROMBOCYTOSIS

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) 9 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 18 DEC 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 True

Hospital Admission Date (dd MMM yyyy) 9 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 18 DEC 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	
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

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

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

Yes

No

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

Name of Medication TURMERIC

Prophylaxis Yes
No

Indication CHRONIC BACK PAIN

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

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US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

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 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

Name of Medication ZINC

Prophylaxis Yes
No

Indication SARS-COV-2

Dose per administration UNK

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

	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*) _____ 08 DEC 2020

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

Name of Medication OXYGEN

Prophylaxis Yes
No

Indication SARS-COV-2

Dose per administration UNK

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify LITERS

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

	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*) 18 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

Name of Medication DEXAMETHASONE

Prophylaxis Yes
No

Indication THROMBOCYTOSIS

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
	If route of administration is Other, specify	
	Start date (dd MMM yyyy)	09 DEC 2020
	Start date completely unknown	False
	Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
	If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020
	Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/> No <input 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"/>

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

Name of Medication REMDESIVIR

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 100

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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US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:36:23

Generated On: 09 Jun 2021 14:59:24

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
	If route of administration is Other, specify	
	Start date (<i>dd MMM yyyy</i>)	9 DEC 2020
	Start date completely unknown	False
	Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
	If not Ongoing, End date (<i>dd MMM yyyy</i>)	18 DEC 2020
	Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/> No <input 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"/>

US3052315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 16:53:50

Generated On: 09 Jun 2021 14:59:24

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3052315

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:24

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

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/DEC/2020 05:53
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.	<input checked="" type="checkbox"/> True

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/DEC/2020 14:30
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.	<input checked="" type="checkbox"/> True

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/JAN/2021 09:31
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

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/FEB/2021 21:38
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.	<input checked="" type="checkbox"/> True

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/MAR/2021 12:19
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.	<input checked="" type="checkbox"/> True

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/APR/2021 15:04
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.	<input checked="" type="checkbox"/> True

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/APR/2021 09:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 12:27:19

Generated On: 09 Jun 2021 14:59:24

SAEID	USA-US117-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/APR/2021 07:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3052315 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052315

Form: Participant Creation

Generated On: 09 Jun 2021 14:59:24

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:50:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'US3052315'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:29:47

US3052315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:36
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:20:56
User entered 'Yes (Y)'		02 Sep 2020 12:12:39

US3052315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:36
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:20:56
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:29:48

US3052315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:36
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:20:56
User entered 'Clinic (Clinic)'		02 Sep 2020 12:12:39

US3052315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:07:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'SCRN'	System	02 Sep 2020 12:12:39

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:29:49

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '65'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User entered 'YEARS'	System	02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:07:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '65'	System	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered 'Male (M)'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered 'I'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:07:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered empty.		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:07:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:42
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:16
User entered '0'		02 Sep 2020 12:11:42

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered '28 Aug 2020'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:07:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Aug 2020'	System	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User entered '2020'	System	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered 'Amendment 3 (3)'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered empty.	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered empty.	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:14

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:31
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:29:48

US3052315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:48
Data hard locked.		03 Apr 2021 08:27:58
User entered '1'	System	28 Aug 2020 20:37:21

US3052315

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:07:54
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:42
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:21

US3052315

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:59:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:22:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:08:21

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:45:48
Data point term sent to Coder	System	26 Oct 2020 19:14:19
Coding entries removed.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:13:29
User entered 'CHRONIC BACK PAIN' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:13:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:10:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:10:39
Data point term sent to Coder	System	02 Sep 2020 12:09:41
User entered 'Chronic back pain'	(b) (4), (b) (6)	02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'UN Dec 2019'		02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'		02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'Yes (Y)'		02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered empty.		02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Dec 2019'	System	02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered '2019'	System	02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered empty.	System	02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered empty.	System	02 Sep 2020 12:09:01

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Cervical disc herniation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:45:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:45:27
Data point term sent to Coder	System	26 Oct 2020 19:14:19
User entered 'herniated disc in neck'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'un UNK 1995'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'un UNK 1995'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Jan 1995'	System	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered '1995'	System	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered 'Jan 1995'	System	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '1995'	System	26 Oct 2020 19:14:12

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:58:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:58:29
Data point term sent to Coder	System	26 Oct 2020 19:15:21
User entered 'disc fusion in neck'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'un UNK 1995'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Oct 2020 19:35:49
User entered 'Un UNK 1995' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:35:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Oct 2020 19:14:48
User entered 'u UNK 1995' (non-conformant).	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Jan 1995'	System	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered '1995'	System	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered 'Jan 1995'	System	26 Oct 2020 19:35:49
User entered empty.	System	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered '1995'	System	26 Oct 2020 19:35:49
User entered empty.	System	26 Oct 2020 19:14:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Atrial septal defect, LLT: Congenital atrial septal defect - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:47:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:47:28
Data point term sent to Coder	System	26 Oct 2020 19:37:40
User entered 'congenital atrial septal defect'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'un UNK 1980'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Jan 1980'	System	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '1980'	System	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User entered empty.		26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered empty.	System	26 Oct 2020 19:36:48

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:14:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:14:30
Data point term sent to Coder	System	26 Oct 2020 19:38:44
User entered 'shoulder surgery (right)- rotator cuff'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'un UNK 2006'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered 'un UNK 2006'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:10
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Jan 2006'	System	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '2006'	System	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'Jan 2006'	System	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '2006'	System	26 Oct 2020 19:37:45

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered 'Yes (Y)'		02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered '28 Aug 2020'		02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered '10:56'		02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User entered '28 Aug 2020 10:56'	System	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered '186' cm		02 Sep 2020 12:13:36
DataPoint set to visible.	System	28 Aug 2020 20:37:21

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered '109.09' kg		02 Sep 2020 12:13:36
DataPoint set to visible.	System	28 Aug 2020 20:37:21

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User entered '31.53255'	System	02 Sep 2020 12:13:36
DataPoint set to visible.	System	28 Aug 2020 20:37:21

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User entered 'kg/m2'		02 Sep 2020 12:13:36
DataPoint set to visible.	System	28 Aug 2020 20:37:21

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Note that when ND is recorded for TEMPERATURE, the unit should not remain. The vitals prior to dosing are to be recorded in the Pre-dose in the Vital signs-Dosing page in the Day 1 folder. Please review and update as appropriate. ' (Site from DM).		28 Oct 2020 19:20:20
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Note that when ND is recorded for TEMPERATURE, the unit should not remain. The vitals prior to dosing are to be recorded in the Pre-dose in the Vital signs-Dosing page in the Day 1 folder. Please review and update as appropriate. ' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:04

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Note that when ND is recorded for TEMPERATURE, the unit should not remain. The vitals prior to dosing are to be recorded in the Pre-dose in the Vital signs-Dosing page in the Day 1 folder. Please review and update as appropriate. ' (Site from DM). User entered '98.7' F	(b) (4), (b) (6)	09 Oct 2020 11:46:50
	(b) (4), (b) (6)	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered empty.		02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:04
User entered '70'	(b) (4), (b) (6)	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'bpm'	System	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:04
User entered '22'	(b) (4), (b) (6)	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered 'breaths/min'	System	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:04
User entered '138'	(b) (4), (b) (6)	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User entered 'mmHg'	System	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:04
User entered '83'	(b) (4), (b) (6)	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58
User entered 'mmHg'	System	02 Sep 2020 12:13:36

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58

US3052315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:19
Data hard locked.		03 Apr 2021 08:27:58

US3052315

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:08:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:14:09

US3052315

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:37
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:27:56
User entered '28 Aug 2020'		02 Sep 2020 12:14:09

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'No (N)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'Yes (Y)'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered 'Retired'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered '0'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered '0'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered '0'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

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)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered '0'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered '1'		02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:11:04

US3052315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:01
Data hard unlocked.		07 Apr 2021 07:08:49
Data hard locked.		03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:28:05
User entered empty.		02 Sep 2020 12:11:04

US3052315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:00
User entered 'Yes (Y)'		02 Sep 2020 12:12:27

US3052315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:00
User entered '28 Aug 2020'		02 Sep 2020 12:12:27

US3052315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:00
User entered 'Clinic (Clinic)'		02 Sep 2020 12:12:27

US3052315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'VISIT1'	System	02 Sep 2020 12:12:27

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:35

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered '188849'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:35

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:35

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Nov 2020 18:29:54
User entered 'No (N)'		02 Sep 2020 12:12:08

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered 'No (N)'		02 Sep 2020 12:12:08

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered 'No (N)'		02 Sep 2020 12:12:08

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered 'No (N)'		02 Sep 2020 12:12:08

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered 'No (N)'		02 Sep 2020 12:12:08

US3052315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:24

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:29:54
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:26:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:26:25

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' (Site from DM).		28 Oct 2020 19:19:42
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:39:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:45
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:06:14
User entered '186' cm		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:45
User entered '109.09' kg	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' (Site from DM).		28 Oct 2020 19:19:42
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:39:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:45
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:06:14
User entered '186' cm		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:45
User entered '109.09' kg	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded at Visit 1 Day 1. Please update accordingly.' (Site from DM).		28 Oct 2020 19:20:00
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded at Visit 1 Day 1. Please update accordingly.'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:27
answered with 'screening and day 1 same day. updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded at Visit 1 Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:06:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '28 Aug 2020' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '10:56' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered '28 Aug 2020 10:56'	System	26 Oct 2020 19:40:09
User entered empty.	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '98.7' F reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered empty.		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '70' reason for change: Data Entry Error	Avia McClain-Stocker	26 Oct 2020 19:40:09
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'bpm'	System	26 Oct 2020 19:40:09
User entered empty.	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '22' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'breaths/min'	System	26 Oct 2020 19:40:09
User entered empty.	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '138' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'mmHg'	System	26 Oct 2020 19:40:09
User entered empty.	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '83' reason for change: Data Entry Error	Avia McClain-Stocker	26 Oct 2020 19:40:09
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'mmHg'	System	26 Oct 2020 19:40:09
User entered empty.	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' (Site from DM).		28 Oct 2020 19:19:42
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:39:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:45
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:06:14
User entered '186' cm	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:38:45
User entered '109.09' kg	(b) (4), (b) (6)	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User accepted default value 'Post-Dose (POSTDOSE)'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered 'Yes (Y)'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '28 Aug 2020'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '12:26'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered '28 Aug 2020 12:26'	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '98.3' F		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered 'Oral (Oral)'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered empty.		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '66'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'bpm'	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '15'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'breaths/min'	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '132'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'mmHg'	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:26
User entered '88'		02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'mmHg'	System	02 Sep 2020 12:16:12

US3052315

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:49
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 12:13:54

US3052315

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:31:49
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:40:57
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 12:13:54

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:02
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:02
User entered empty.	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:02
User entered empty.	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'MRNA-1273 OR PLACEBO'	(b)	28 Aug 2020 20:37:50

(

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:02
User entered '28 Aug 2020'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:02
User entered '11:48'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered '28 Aug 2020 11:48'	System	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:02
User entered 'Left Arm (LEFT ARM)'	amy sheets (b) (4) (b) (4)	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
DataPoint Verified.		16 Nov 2020 18:32:02
User entered 'ONCE'	System	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 20:37:50

US3052315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:12
User entered 'Yes (Y)'		02 Sep 2020 12:14:46

US3052315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:12
User entered '28 Aug 2020'		02 Sep 2020 12:14:46

US3052315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:12
User entered '11:35'		02 Sep 2020 12:14:46

US3052315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered '28 Aug 2020 11:35'	System	02 Sep 2020 12:14:46

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:23
User entered '28 Aug 2020'		02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:23
User entered 'Yes (Y)'		02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:23
User entered '11:44'		02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered '28 Aug 2020 11:44'	System	02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:23
User entered 'No (N)'		02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:23
User entered empty.		02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered empty.	System	02 Sep 2020 12:15:00

US3052315

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:32:47
User entered 'Yes (Y)'		25 Sep 2020 15:37:54

US3052315

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:20
User entered '1'	System	25 Sep 2020 15:37:54

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 12:08'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 14:38'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:56:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ef9f9820-b76c-4072-842f-dc148e8db595'	System	28 Aug 2020 20:56:50
User entered 'Yes (Y)'	System	28 Aug 2020 20:56:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:56:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ef9f9820-b76c-4072-842f-dc148e8db595' User entered '98.3'	System	28 Aug 2020 20:56:50
	System	28 Aug 2020 20:56:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:56:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ef9f9820-b76c-4072-842f-dc148e8db595'	System	28 Aug 2020 20:56:50
User entered 'No (N)'	System	28 Aug 2020 20:56:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:56:47', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ef9f9820-b76c-4072-842f-dc148e8db595'	System	28 Aug 2020 20:56:50
User entered '28 Aug 2020 16:56'	System	28 Aug 2020 20:56:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 2'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:08', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fdb77218-1df5-4f08-821e-cb3acc1c1500'	System	30 Aug 2020 00:04:32
User entered 'Yes (Y)'	System	30 Aug 2020 00:04:32

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fdb77218-1df5-4f08-821e-cb3acc1c1500'	System	30 Aug 2020 00:04:32
User entered '98.2'	System	30 Aug 2020 00:04:32

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:20', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fdb77218-1df5-4f08-821e-cb3acc1c1500'	System	30 Aug 2020 00:04:32
User entered 'No (N)'	System	30 Aug 2020 00:04:32

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:30', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fdb77218-1df5-4f08-821e-cb3acc1c1500'	System	30 Aug 2020 00:04:32
User entered '29 Aug 2020 20:04'	System	30 Aug 2020 00:04:32

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 3'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:05', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '52aca318-ef15-4ddb-8e88-9232313b1d50' User entered 'Yes (Y)'	System	30 Aug 2020 16:01:51
	System	30 Aug 2020 16:01:51

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:13', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '52aca318-ef15-4ddb-8e88-9232313b1d50' User entered '98.5'	System	30 Aug 2020 16:01:51
	System	30 Aug 2020 16:01:51

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '52aca318-ef15-4ddb-8e88-9232313b1d50' User entered 'No (N)'	System	30 Aug 2020 16:01:51
	System	30 Aug 2020 16:01:51

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '52aca318-ef15-4ddb-8e88-9232313b1d50' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:01:51
	System	30 Aug 2020 16:01:51

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 4'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:12', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e52306e7-b35b-46f1-806b-dcbdf1929c36' User entered 'Yes (Y)'	System	01 Sep 2020 10:33:31
	System	01 Sep 2020 10:33:31

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:19', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e52306e7-b35b-46f1-806b-dcbdf1929c36' User entered '98.3'	System	01 Sep 2020 10:33:31
	System	01 Sep 2020 10:33:31

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:22', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e52306e7-b35b-46f1-806b-dcbdf1929c36'	System	01 Sep 2020 10:33:31
User entered 'No (N)'	System	01 Sep 2020 10:33:31

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:27', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e52306e7-b35b-46f1-806b-dcbdf1929c36' User entered '01 Sep 2020 06:33'	System	01 Sep 2020 10:33:31
	System	01 Sep 2020 10:33:31

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 5'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:21:24', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c5524e1b-e5cc-4aa1-8e82-1ad2270d6854' User entered 'Yes (Y)'	System	02 Sep 2020 11:21:56
	System	02 Sep 2020 11:21:56

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:21:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c5524e1b-e5cc-4aa1-8e82-1ad2270d6854' User entered '98.5'	System	02 Sep 2020 11:21:56
	System	02 Sep 2020 11:21:56

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:21:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c5524e1b-e5cc-4aa1-8e82-1ad2270d6854' User entered 'No (N)'	System	02 Sep 2020 11:21:56
	System	02 Sep 2020 11:21:56

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:21:52', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c5524e1b-e5cc-4aa1-8e82-1ad2270d6854' User entered '02 Sep 2020 07:21'	System	02 Sep 2020 11:21:56
	System	02 Sep 2020 11:21:56

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 6'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93876aef-e21a-46f0-8fa0-38cf339a454b' User entered 'Yes (Y)'	System	02 Sep 2020 16:00:54
	System	02 Sep 2020 16:00:54

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:30', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93876aef-e21a-46f0-8fa0-38cf339a454b' User entered '98.3'	System	02 Sep 2020 16:00:54
	System	02 Sep 2020 16:00:54

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:33', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93876aef-e21a-46f0-8fa0-38cf339a454b'	System	02 Sep 2020 16:00:54
User entered 'No (N)'	System	02 Sep 2020 16:00:54

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:36', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93876aef-e21a-46f0-8fa0-38cf339a454b' User entered '02 Sep 2020 12:00'	System	02 Sep 2020 16:00:54
	System	02 Sep 2020 16:00:54

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 7'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:30', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6961e2fb-9d9c-49b5-9f83-d72288040343' User entered 'Yes (Y)'	System	03 Sep 2020 16:51:44
	System	03 Sep 2020 16:51:44

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:36', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6961e2fb-9d9c-49b5-9f83-d72288040343' User entered '98.7'	System	03 Sep 2020 16:51:44
	System	03 Sep 2020 16:51:44

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:39', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6961e2fb-9d9c-49b5-9f83-d72288040343' User entered 'No (N)'	System	03 Sep 2020 16:51:44
	System	03 Sep 2020 16:51:44

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:42', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6961e2fb-9d9c-49b5-9f83-d72288040343' User entered '03 Sep 2020 12:51'	System	03 Sep 2020 16:51:44
	System	03 Sep 2020 16:51:44

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 12:08'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 14:38'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:04', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a66c97cf-e31c-4fa8-9665-64ce9ce58eb4' User entered 'None (1)'	System	28 Aug 2020 20:57:31
	System	28 Aug 2020 20:57:31

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:11', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a66c97cf-e31c-4fa8-9665-64ce9ce58eb4'	System	28 Aug 2020 20:57:31
User entered 'No (N)'	System	28 Aug 2020 20:57:31

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:14', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a66c97cf-e31c-4fa8-9665-64ce9ce58eb4' User entered 'No (N)'	System	28 Aug 2020 20:57:31
	System	28 Aug 2020 20:57:31

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a66c97cf-e31c-4fa8-9665-64ce9ce58eb4'	System	28 Aug 2020 20:57:31
User entered 'None (1)'	System	28 Aug 2020 20:57:31

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:28', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a66c97cf-e31c-4fa8-9665-64ce9ce58eb4' User entered '28 Aug 2020 16:57'	System	28 Aug 2020 20:57:31
	System	28 Aug 2020 20:57:31

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 2'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:38', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d5016f9-9d2a-49f1-969f-3563aa49482a' User entered 'None (1)'	System	30 Aug 2020 00:05:01
	System	30 Aug 2020 00:05:01

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d5016f9-9d2a-49f1-969f-3563aa49482a' User entered 'No (N)'	System	30 Aug 2020 00:05:01
	System	30 Aug 2020 00:05:01

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d5016f9-9d2a-49f1-969f-3563aa49482a' User entered 'No (N)'	System	30 Aug 2020 00:05:01
	System	30 Aug 2020 00:05:01

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d5016f9-9d2a-49f1-969f-3563aa49482a'	System	30 Aug 2020 00:05:01
User entered 'None (1)'	System	30 Aug 2020 00:05:01

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:04:55', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d5016f9-9d2a-49f1-969f-3563aa49482a' User entered '29 Aug 2020 20:04'	System	30 Aug 2020 00:05:01
	System	30 Aug 2020 00:05:01

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 3'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:29', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f220c9f0-f6d4-4ee3-af19-24acd2f9ac54'	System	30 Aug 2020 16:02:17
User entered 'None (1)'	System	30 Aug 2020 16:02:17

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f220c9f0-f6d4-4ee3-af19-24acd2f9ac54'	System	30 Aug 2020 16:02:17
User entered 'No (N)'	System	30 Aug 2020 16:02:17

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f220c9f0-f6d4-4ee3-af19-24acd2f9ac54'	System	30 Aug 2020 16:02:17
User entered 'No (N)'	System	30 Aug 2020 16:02:17

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f220c9f0-f6d4-4ee3-af19-24acd2f9ac54'	System	30 Aug 2020 16:02:17
User entered 'None (1)'	System	30 Aug 2020 16:02:17

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:45', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f220c9f0-f6d4-4ee3-af19-24acd2f9ac54' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:02:17
	System	30 Aug 2020 16:02:17

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 4'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '9cb8e3c6-fa7d-441e-b52b-21b70cd85240' User entered 'None (1)'	System	01 Sep 2020 10:33:47
	System	01 Sep 2020 10:33:47

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:34', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '9cb8e3c6-fa7d-441e-b52b-21b70cd85240' User entered 'No (N)'	System	01 Sep 2020 10:33:47
	System	01 Sep 2020 10:33:47

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '9cb8e3c6-fa7d-441e-b52b-21b70cd85240' User entered 'No (N)'	System	01 Sep 2020 10:33:47
	System	01 Sep 2020 10:33:47

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '9cb8e3c6-fa7d-441e-b52b-21b70cd85240'	System	01 Sep 2020 10:33:47
User entered 'None (1)'	System	01 Sep 2020 10:33:47

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '9cb8e3c6-fa7d-441e-b52b-21b70cd85240' User entered '01 Sep 2020 06:33'	System	01 Sep 2020 10:33:47
	System	01 Sep 2020 10:33:47

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 5'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:21:59', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ad35c125-fe40-441f-a430-5114b9cbb482'	System	02 Sep 2020 11:22:19
User entered 'None (1)'	System	02 Sep 2020 11:22:19

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:05', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ad35c125-fe40-441f-a430-5114b9cbb482'	System	02 Sep 2020 11:22:19
User entered 'No (N)'	System	02 Sep 2020 11:22:19

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:09', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ad35c125-fe40-441f-a430-5114b9cbb482'	System	02 Sep 2020 11:22:19
User entered 'No (N)'	System	02 Sep 2020 11:22:19

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:13', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ad35c125-fe40-441f-a430-5114b9cbb482'	System	02 Sep 2020 11:22:19
User entered 'None (1)'	System	02 Sep 2020 11:22:19

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:17', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'ad35c125-fe40-441f-a430-5114b9cbb482' User entered '02 Sep 2020 07:22'	System	02 Sep 2020 11:22:19
	System	02 Sep 2020 11:22:19

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 6'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7bcb9f50-8735-4abf-8da5-a05c2eea5d7b'	System	02 Sep 2020 16:01:27
User entered 'None (1)'	System	02 Sep 2020 16:01:27

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:43', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7bcb9f50-8735-4abf-8da5-a05c2eea5d7b'	System	02 Sep 2020 16:01:27
User entered 'No (N)'	System	02 Sep 2020 16:01:27

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7bcb9f50-8735-4abf-8da5-a05c2eea5d7b'	System	02 Sep 2020 16:01:27
User entered 'No (N)'	System	02 Sep 2020 16:01:27

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:52', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7bcb9f50-8735-4abf-8da5-a05c2eea5d7b'	System	02 Sep 2020 16:01:27
User entered 'None (1)'	System	02 Sep 2020 16:01:27

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:00:58', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7bcb9f50-8735-4abf-8da5-a05c2eea5d7b' User entered '02 Sep 2020 12:00'	System	02 Sep 2020 16:01:27
	System	02 Sep 2020 16:01:27

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 7'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c1ce2746-832b-4a74-952a-29f9798b5147'	System	03 Sep 2020 16:52:07
User entered 'None (1)'	System	03 Sep 2020 16:52:07

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:50', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c1ce2746-832b-4a74-952a-29f9798b5147'	System	03 Sep 2020 16:52:07
User entered 'No (N)'	System	03 Sep 2020 16:52:07

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:51:56', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c1ce2746-832b-4a74-952a-29f9798b5147'	System	03 Sep 2020 16:52:07
User entered 'No (N)'	System	03 Sep 2020 16:52:07

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:01', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c1ce2746-832b-4a74-952a-29f9798b5147'	System	03 Sep 2020 16:52:07
User entered 'None (1)'	System	03 Sep 2020 16:52:07

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:04', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c1ce2746-832b-4a74-952a-29f9798b5147'	System	03 Sep 2020 16:52:07
User entered '03 Sep 2020 12:52'	System	03 Sep 2020 16:52:07

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 12:08'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 14:38'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007'	System	28 Aug 2020 20:58:20
User entered 'None (0)'	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007'	System	28 Aug 2020 20:58:20
User entered 'None (0)'	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:52', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007'	System	28 Aug 2020 20:58:20
User entered 'None (0)'	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:57:56', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007' User entered 'None (0)'	System	28 Aug 2020 20:58:20
	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:58:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007'	System	28 Aug 2020 20:58:20
User entered 'None (0)'	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:58:04', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007'	System	28 Aug 2020 20:58:20
User entered 'None (0)'	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:58:10', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007'	System	28 Aug 2020 20:58:20
User entered 'No (N)'	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-28T16:58:17', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '092842b0-63da-47e2-893e-910452213007' User entered '28 Aug 2020 16:58'	System	28 Aug 2020 20:58:20
	System	28 Aug 2020 20:58:20

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 2'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:02', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'None (0)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:05', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'None (0)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:07', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'None (0)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:12', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'None (0)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'None (0)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:19', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'None (0)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:24', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered 'No (N)'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-29T20:05:28', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b2edc37c-758b-4208-afe3-a64c7886057a' User entered '29 Aug 2020 20:05'	System	30 Aug 2020 00:05:33
	System	30 Aug 2020 00:05:33

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 3'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'None (0)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:52', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'None (0)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'None (0)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:56', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'None (0)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:01:59', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'None (0)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:02:02', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'None (0)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:02:06', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered 'No (N)'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-08-30T12:02:12', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5364a22d-e99b-4df8-93fa-e6838a6e6458' User entered '30 Aug 2020 12:02'	System	30 Aug 2020 16:02:47
	System	30 Aug 2020 16:02:47

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 4'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'None (0)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'None (0)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:56', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'None (0)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:33:59', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'None (0)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:34:01', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'None (0)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:34:04', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'None (0)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:34:06', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered 'No (N)'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-01T06:34:09', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b85a3613-1832-4379-80ea-98bcf8503ac6' User entered '01 Sep 2020 06:34'	System	01 Sep 2020 10:34:14
	System	01 Sep 2020 10:34:14

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 5'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:22', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered 'None (0)'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:24', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered 'None (0)'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:26', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered 'None (0)'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:29', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered 'None (0)'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered 'None (0)'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:36', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered 'None (0)'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d'	System	02 Sep 2020 11:22:48
User entered 'No (N)'	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T07:22:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'b119138f-cc96-4815-bc5a-f1c5de77f14d' User entered '02 Sep 2020 07:22'	System	02 Sep 2020 11:22:48
	System	02 Sep 2020 11:22:48

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 6'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:30', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541'	System	02 Sep 2020 16:03:34
User entered 'None (0)'	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541'	System	02 Sep 2020 16:03:34
User entered 'None (0)'	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:34', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541'	System	02 Sep 2020 16:03:34
User entered 'None (0)'	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541' User entered 'None (0)'	System	02 Sep 2020 16:03:34
	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541' User entered 'None (0)'	System	02 Sep 2020 16:03:34
	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541'	System	02 Sep 2020 16:03:34
User entered 'None (0)'	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:50', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541' User entered 'No (N)'	System	02 Sep 2020 16:03:34
	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-02T12:02:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '22dbfe16-fb7f-4cc1-95b5-0a903e93b541'	System	02 Sep 2020 16:03:34
User entered '02 Sep 2020 12:02'	System	02 Sep 2020 16:03:34

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 7'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:09', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'None (0)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:11', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'None (0)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:14', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'None (0)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'None (0)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:19', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'None (0)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'None (0)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:24', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered 'No (N)'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-03T12:52:27', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f095af45-297f-4b41-8fad-60c2d22debae' User entered '03 Sep 2020 12:52'	System	03 Sep 2020 16:52:30
	System	03 Sep 2020 16:52:30

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:37:50

US3052315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:25
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:12:20

US3052315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:25
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).		28 Oct 2020 19:20:38
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 of attempt' (Site from System).	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:12:41
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	26 Oct 2020 19:12:20
User entered '8 Sep 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:12:20

US3052315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:25
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:12:20

US3052315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:25
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:12:20

US3052315

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:59
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:16

US3052315

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '1'	System	25 Sep 2020 15:38:16

US3052315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:24
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:42:57

US3052315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:24
User entered '14 Sep 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:42:57

US3052315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:24
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:42:57

US3052315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:24
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:42:57

US3052315

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:44
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:24

US3052315

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:58
User entered '1'	System	25 Sep 2020 15:38:24

US3052315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:08:13
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:43:44

US3052315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:08:13
User entered '21 Sep 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:43:44

US3052315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:08:13
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:43:44

US3052315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:08:13
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:43:44

US3052315

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:08:20
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:32

US3052315

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:50
User entered '1'	System	25 Sep 2020 15:38:32

US3052315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:52:25
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:49

US3052315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:52:25
User entered '25 Sep 2020'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:49

US3052315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[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 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:52:25
User entered 'Clinic (Clinic)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:49

US3052315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'VISIT2'	System	25 Sep 2020 15:38:49

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User accepted default value 'Pre-Dose (PREDOSE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '25 Sep 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '10:18'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '25 Sep 2020 10:18'	System	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '36.9' C	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered 'Oral (Oral)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '69'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'bpm'	System	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '14'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'breaths/min'	System	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '127'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'mmHg'	System	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '81'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'mmHg'	System	26 Oct 2020 19:44:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User accepted default value 'Post-Dose (POSTDOSE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '25 Sep 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '11:49'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '25 Sep 2020 11:49'	System	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '98.2' F	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered 'Oral (Oral)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '66'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'bpm'	System	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '14'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'breaths/min'	System	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '124'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'mmHg'	System	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:53:56
User entered '84'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'mmHg'	System	26 Oct 2020 19:45:45

US3052315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:54:10
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:54:10
User entered '25 Sep 2020'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:38:58

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:30
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:30
User entered empty.	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

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 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:30
User entered empty.	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:30
User entered '25 Sep 2020'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:30
User entered '11:19'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '25 Sep 2020 11:19'	System	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:30
User entered 'Left Arm (LEFT ARM)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
DataPoint Verified.		14 Dec 2020 17:04:30
User entered 'ONCE'	System	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 15:39:52

US3052315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:47
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:18

US3052315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:47
User entered '25 Sep 2020'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:18

US3052315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:47
User entered '11:14'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:18

US3052315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '25 Sep 2020 11:14'	System	25 Sep 2020 15:40:18

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:54
User entered '25 Sep 2020'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:54
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:54
User entered '11:17'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '25 Sep 2020 11:17'	System	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:54
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:04:54
User entered empty.	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered empty.	System	25 Sep 2020 15:40:36

US3052315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:05:07
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	25 Sep 2020 15:40:44

US3052315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '1'	System	25 Sep 2020 15:40:44

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:50:56', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5823e17f-45ad-486f-978b-3ef0bf026c9d' User entered 'Yes (Y)'	System	25 Sep 2020 15:52:14
	System	25 Sep 2020 15:52:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:51:03', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5823e17f-45ad-486f-978b-3ef0bf026c9d' User entered '98.2'	System	25 Sep 2020 15:52:14
	System	25 Sep 2020 15:52:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:51:06', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5823e17f-45ad-486f-978b-3ef0bf026c9d'	System	25 Sep 2020 15:52:14
User entered 'No (N)'	System	25 Sep 2020 15:52:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:09', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5823e17f-45ad-486f-978b-3ef0bf026c9d' User entered '25 Sep 2020 11:52'	System	25 Sep 2020 15:52:14
	System	25 Sep 2020 15:52:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 14:09'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:54:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6c09cc99-68bd-49f8-ae14-335b25787903'	System	26 Sep 2020 13:55:00
User entered 'Yes (Y)'	System	26 Sep 2020 13:55:00

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:54:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6c09cc99-68bd-49f8-ae14-335b25787903' User entered '98.4'	System	26 Sep 2020 13:55:00
	System	26 Sep 2020 13:55:00

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:54:54', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6c09cc99-68bd-49f8-ae14-335b25787903'	System	26 Sep 2020 13:55:00
User entered 'No (N)'	System	26 Sep 2020 13:55:00

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:54:58', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '6c09cc99-68bd-49f8-ae14-335b25787903' User entered '26 Sep 2020 09:54'	System	26 Sep 2020 13:55:00
	System	26 Sep 2020 13:55:00

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 15:04'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 2'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:00:54', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c14cb160-a3b9-42d5-b242-cbf4d1539a4d' User entered 'Yes (Y)'	System	26 Sep 2020 16:01:54
	System	26 Sep 2020 16:01:54

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:02', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c14cb160-a3b9-42d5-b242-cbf4d1539a4d' User entered '98.4'	System	26 Sep 2020 16:01:54
	System	26 Sep 2020 16:01:54

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:05', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c14cb160-a3b9-42d5-b242-cbf4d1539a4d' User entered 'No (N)'	System	26 Sep 2020 16:01:54
	System	26 Sep 2020 16:01:54

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:13', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'c14cb160-a3b9-42d5-b242-cbf4d1539a4d' User entered '26 Sep 2020 12:01'	System	26 Sep 2020 16:01:54
	System	26 Sep 2020 16:01:54

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 3'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:12', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5cc29647-64a2-4d81-bae8-133c76aa7e1f' User entered 'Yes (Y)'	System	27 Sep 2020 16:11:32
	System	27 Sep 2020 16:11:32

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:19', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5cc29647-64a2-4d81-bae8-133c76aa7e1f' User entered '98.4'	System	27 Sep 2020 16:11:32
	System	27 Sep 2020 16:11:32

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:26', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5cc29647-64a2-4d81-bae8-133c76aa7e1f' User entered 'No (N)'	System	27 Sep 2020 16:11:32
	System	27 Sep 2020 16:11:32

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:30', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5cc29647-64a2-4d81-bae8-133c76aa7e1f' User entered '27 Sep 2020 12:11'	System	27 Sep 2020 16:11:32
	System	27 Sep 2020 16:11:32

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 4'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:04', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fa61b064-b520-46c2-8161-56c9575e9bc1' User entered 'Yes (Y)'	System	28 Sep 2020 20:14:23
	System	28 Sep 2020 20:14:23

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:13', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fa61b064-b520-46c2-8161-56c9575e9bc1' User entered '98.3'	System	28 Sep 2020 20:14:23
	System	28 Sep 2020 20:14:23

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fa61b064-b520-46c2-8161-56c9575e9bc1' User entered 'No (N)'	System	28 Sep 2020 20:14:23
	System	28 Sep 2020 20:14:23

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fa61b064-b520-46c2-8161-56c9575e9bc1' User entered '28 Sep 2020 16:14'	System	28 Sep 2020 20:14:23
	System	28 Sep 2020 20:14:23

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 5'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:35:58', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'af92d6f5-3d53-4d32-bb78-4f3f71e2b658' User entered 'Yes (Y)'	System	30 Sep 2020 13:36:14
	System	30 Sep 2020 13:36:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:05', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'af92d6f5-3d53-4d32-bb78-4f3f71e2b658' User entered '98.3'	System	30 Sep 2020 13:36:14
	System	30 Sep 2020 13:36:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:08', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'af92d6f5-3d53-4d32-bb78-4f3f71e2b658'	System	30 Sep 2020 13:36:14
User entered 'No (N)'	System	30 Sep 2020 13:36:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:11', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'af92d6f5-3d53-4d32-bb78-4f3f71e2b658'	System	30 Sep 2020 13:36:14
User entered '30 Sep 2020 09:36'	System	30 Sep 2020 13:36:14

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 6'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:01:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5c18f656-a340-4693-bae8-d5ab25a513f5' User entered 'Yes (Y)'	System	30 Sep 2020 16:02:42
	System	30 Sep 2020 16:02:42

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:01:42', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5c18f656-a340-4693-bae8-d5ab25a513f5' User entered '98.4'	System	30 Sep 2020 16:02:42
	System	30 Sep 2020 16:02:42

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:01:45', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5c18f656-a340-4693-bae8-d5ab25a513f5' User entered 'No (N)'	System	30 Sep 2020 16:02:42
	System	30 Sep 2020 16:02:42

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:01:48', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5c18f656-a340-4693-bae8-d5ab25a513f5' User entered '30 Sep 2020 12:01'	System	30 Sep 2020 16:02:42
	System	30 Sep 2020 16:02:42

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 7'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'edd15468-002d-4149-a879-e38190fa368a' User entered 'Yes (Y)'	System	01 Oct 2020 21:03:37
	System	01 Oct 2020 21:03:37

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:25', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'edd15468-002d-4149-a879-e38190fa368a' User entered '98.6'	System	01 Oct 2020 21:03:37
	System	01 Oct 2020 21:03:37

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:30', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'edd15468-002d-4149-a879-e38190fa368a' User entered 'No (N)'	System	01 Oct 2020 21:03:37
	System	01 Oct 2020 21:03:37

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:33', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'edd15468-002d-4149-a879-e38190fa368a' User entered '01 Oct 2020 17:03'	System	01 Oct 2020 21:03:37
	System	01 Oct 2020 21:03:37

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:22', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '66643833-ed77-4d18-81d9-736344cc76e9'	System	25 Sep 2020 15:52:37
User entered 'None (1)'	System	25 Sep 2020 15:52:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:25', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '66643833-ed77-4d18-81d9-736344cc76e9'	System	25 Sep 2020 15:52:37
User entered 'No (N)'	System	25 Sep 2020 15:52:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:28', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '66643833-ed77-4d18-81d9-736344cc76e9'	System	25 Sep 2020 15:52:37
User entered 'No (N)'	System	25 Sep 2020 15:52:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '66643833-ed77-4d18-81d9-736344cc76e9'	System	25 Sep 2020 15:52:37
User entered 'None (1)'	System	25 Sep 2020 15:52:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '66643833-ed77-4d18-81d9-736344cc76e9' User entered '25 Sep 2020 11:52'	System	25 Sep 2020 15:52:37
	System	25 Sep 2020 15:52:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 14:09'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:11', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f4bc608a-2328-4d6f-bb29-212fb7d03ee7'	System	26 Sep 2020 13:55:36
User entered 'None (1)'	System	26 Sep 2020 13:55:36

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:13', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f4bc608a-2328-4d6f-bb29-212fb7d03ee7' User entered 'No (N)'	System	26 Sep 2020 13:55:36
	System	26 Sep 2020 13:55:36

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:17', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f4bc608a-2328-4d6f-bb29-212fb7d03ee7'	System	26 Sep 2020 13:55:36
User entered 'No (N)'	System	26 Sep 2020 13:55:36

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f4bc608a-2328-4d6f-bb29-212fb7d03ee7'	System	26 Sep 2020 13:55:36
User entered 'None (1)'	System	26 Sep 2020 13:55:36

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f4bc608a-2328-4d6f-bb29-212fb7d03ee7'	System	26 Sep 2020 13:55:36
User entered '26 Sep 2020 09:55'	System	26 Sep 2020 13:55:36

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 15:04'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 2'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93039338-7c0c-4903-81d6-395adf0976c4'	System	26 Sep 2020 16:02:37
User entered 'None (1)'	System	26 Sep 2020 16:02:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93039338-7c0c-4903-81d6-395adf0976c4'	System	26 Sep 2020 16:02:37
User entered 'No (N)'	System	26 Sep 2020 16:02:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:33', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93039338-7c0c-4903-81d6-395adf0976c4'	System	26 Sep 2020 16:02:37
User entered 'No (N)'	System	26 Sep 2020 16:02:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:36', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93039338-7c0c-4903-81d6-395adf0976c4'	System	26 Sep 2020 16:02:37
User entered 'None (1)'	System	26 Sep 2020 16:02:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '93039338-7c0c-4903-81d6-395adf0976c4' User entered '26 Sep 2020 12:01'	System	26 Sep 2020 16:02:37
	System	26 Sep 2020 16:02:37

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 3'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '77b15d08-20ce-427a-8166-3e3f1be91bdf' User entered 'None (1)'	System	27 Sep 2020 16:12:08
	System	27 Sep 2020 16:12:08

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:42', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '77b15d08-20ce-427a-8166-3e3f1be91bdf' User entered 'No (N)'	System	27 Sep 2020 16:12:08
	System	27 Sep 2020 16:12:08

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:50', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '77b15d08-20ce-427a-8166-3e3f1be91bdf' User entered 'No (N)'	System	27 Sep 2020 16:12:08
	System	27 Sep 2020 16:12:08

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:11:54', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '77b15d08-20ce-427a-8166-3e3f1be91bdf' User entered 'None (1)'	System	27 Sep 2020 16:12:08
	System	27 Sep 2020 16:12:08

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:06', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '77b15d08-20ce-427a-8166-3e3f1be91bdf' User entered '27 Sep 2020 12:12'	System	27 Sep 2020 16:12:08
	System	27 Sep 2020 16:12:08

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 4'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:26', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a4a2a168-5a4c-4ac2-a563-1d0f8a705f98'	System	28 Sep 2020 20:14:43
User entered 'None (1)'	System	28 Sep 2020 20:14:43

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:28', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a4a2a168-5a4c-4ac2-a563-1d0f8a705f98'	System	28 Sep 2020 20:14:43
User entered 'No (N)'	System	28 Sep 2020 20:14:43

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a4a2a168-5a4c-4ac2-a563-1d0f8a705f98'	System	28 Sep 2020 20:14:43
User entered 'No (N)'	System	28 Sep 2020 20:14:43

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:33', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a4a2a168-5a4c-4ac2-a563-1d0f8a705f98'	System	28 Sep 2020 20:14:43
User entered 'None (1)'	System	28 Sep 2020 20:14:43

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:38', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a4a2a168-5a4c-4ac2-a563-1d0f8a705f98'	System	28 Sep 2020 20:14:43
User entered '28 Sep 2020 16:14'	System	28 Sep 2020 20:14:43

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 5'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:15', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '330621d9-cbf0-47ae-befb-584841bca3f2'	System	30 Sep 2020 13:36:38
User entered 'None (1)'	System	30 Sep 2020 13:36:38

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:21', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '330621d9-cbf0-47ae-befb-584841bca3f2'	System	30 Sep 2020 13:36:38
User entered 'No (N)'	System	30 Sep 2020 13:36:38

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '330621d9-cbf0-47ae-befb-584841bca3f2'	System	30 Sep 2020 13:36:38
User entered 'No (N)'	System	30 Sep 2020 13:36:38

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:25', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '330621d9-cbf0-47ae-befb-584841bca3f2'	System	30 Sep 2020 13:36:38
User entered 'None (1)'	System	30 Sep 2020 13:36:38

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:28', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '330621d9-cbf0-47ae-befb-584841bca3f2'	System	30 Sep 2020 13:36:38
User entered '30 Sep 2020 09:36'	System	30 Sep 2020 13:36:38

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 6'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:01:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'de6c52af-dacd-465e-be70-3feba5714abc'	System	30 Sep 2020 16:02:56
User entered 'None (1)'	System	30 Sep 2020 16:02:56

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'de6c52af-dacd-465e-be70-3feba5714abc' User entered 'No (N)'	System	30 Sep 2020 16:02:56
	System	30 Sep 2020 16:02:56

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:03', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'de6c52af-dacd-465e-be70-3feba5714abc' User entered 'No (N)'	System	30 Sep 2020 16:02:56
	System	30 Sep 2020 16:02:56

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:07', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'de6c52af-dacd-465e-be70-3feba5714abc'	System	30 Sep 2020 16:02:56
User entered 'None (1)'	System	30 Sep 2020 16:02:56

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:10', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'de6c52af-dacd-465e-be70-3feba5714abc' User entered '30 Sep 2020 12:02'	System	30 Sep 2020 16:02:56
	System	30 Sep 2020 16:02:56

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 7'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '712573a0-4c4e-4cb1-8bae-947bd79d5a76'	System	01 Oct 2020 21:03:53
User entered 'None (1)'	System	01 Oct 2020 21:03:53

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '712573a0-4c4e-4cb1-8bae-947bd79d5a76' User entered 'No (N)'	System	01 Oct 2020 21:03:53
	System	01 Oct 2020 21:03:53

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:42', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '712573a0-4c4e-4cb1-8bae-947bd79d5a76' User entered 'No (N)'	System	01 Oct 2020 21:03:53
	System	01 Oct 2020 21:03:53

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '712573a0-4c4e-4cb1-8bae-947bd79d5a76'	System	01 Oct 2020 21:03:53
User entered 'None (1)'	System	01 Oct 2020 21:03:53

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:52', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '712573a0-4c4e-4cb1-8bae-947bd79d5a76' User entered '01 Oct 2020 17:03'	System	01 Oct 2020 21:03:53
	System	01 Oct 2020 21:03:53

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'None (0)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:43', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'None (0)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:45', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'None (0)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:47', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'None (0)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'None (0)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'None (0)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered 'No (N)'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-25T11:52:57', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '7973c133-28f7-462a-9468-b73701b8c2fd' User entered '25 Sep 2020 11:52'	System	25 Sep 2020 15:53:00
	System	25 Sep 2020 15:53:00

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 14:09'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'None (0)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'None (0)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:39', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'None (0)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'None (0)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:43', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'None (0)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'None (0)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:50', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered 'No (N)'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T09:55:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'f8794689-dca9-4891-aedd-7de41e863539' User entered '26 Sep 2020 09:55'	System	26 Sep 2020 13:55:56
	System	26 Sep 2020 13:55:56

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '25 Sep 2020 15:04'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 2'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:01:57', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered 'None (0)'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:02', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered 'None (0)'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:06', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered 'None (0)'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:18', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered 'None (0)'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:22', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered 'None (0)'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:26', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered 'None (0)'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942'	System	26 Sep 2020 16:03:30
User entered 'No (N)'	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-26T12:02:34', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '5014a8cc-7dd0-4dfc-a86c-e706a5c4b942' User entered '26 Sep 2020 12:02'	System	26 Sep 2020 16:03:30
	System	26 Sep 2020 16:03:30

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 3'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:10', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'None (0)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:12', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'None (0)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:14', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'None (0)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'None (0)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:19', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'None (0)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'None (0)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:31', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered 'No (N)'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-27T12:12:33', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'e3921732-2090-4a2e-a410-b05de36dc0c3' User entered '27 Sep 2020 12:12'	System	27 Sep 2020 16:12:38
	System	27 Sep 2020 16:12:38

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 4'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:43', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'None (0)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:45', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'None (0)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:47', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'None (0)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'None (0)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'None (0)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:54', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'None (0)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:14:57', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered 'No (N)'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-28T16:15:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '46ba04c4-80ad-44f4-ab6a-63de65a990df' User entered '28 Sep 2020 16:15'	System	28 Sep 2020 20:15:04
	System	28 Sep 2020 20:15:04

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 5'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0'	System	30 Sep 2020 13:36:50
User entered 'None (0)'	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:34', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0' User entered 'None (0)'	System	30 Sep 2020 13:36:50
	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:36', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0'	System	30 Sep 2020 13:36:50
User entered 'None (0)'	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0' User entered 'None (0)'	System	30 Sep 2020 13:36:50
	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:39', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0' User entered 'None (0)'	System	30 Sep 2020 13:36:50
	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0' User entered 'None (0)'	System	30 Sep 2020 13:36:50
	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0'	System	30 Sep 2020 13:36:50
User entered 'No (N)'	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T09:36:47', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'fc771e04-1486-4f97-bbae-41af29fb0fa0' User entered '30 Sep 2020 09:36'	System	30 Sep 2020 13:36:50
	System	30 Sep 2020 13:36:50

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 6'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:13', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'None (0)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:14', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'None (0)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:16', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'None (0)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:18', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'None (0)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:20', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'None (0)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:22', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'None (0)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:24', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered 'No (N)'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-09-30T12:02:26', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '38d69e13-ce1e-45ce-beef-254aedb938c5' User entered '30 Sep 2020 12:02'	System	30 Sep 2020 16:03:16
	System	30 Sep 2020 16:03:16

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	25 Sep 2020 15:39:52
User entered 'Day 7'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:57', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'None (0)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:03:58', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'None (0)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'None (0)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:04:02', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'None (0)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:04:04', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'None (0)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:04:05', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'None (0)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:04:08', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered 'No (N)'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-01T17:04:11', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01426ce3-61f3-48d9-969e-996ae5e4cbe9' User entered '01 Oct 2020 17:04'	System	01 Oct 2020 21:04:13
	System	01 Oct 2020 21:04:13

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:39:52

US3052315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:39:52

US3052315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:10:38
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:21

US3052315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:10:38
User entered '5 Oct 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:21

US3052315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:10:38
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:21

US3052315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:10:38
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:21

US3052315

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:10:48
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:12:01

US3052315

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '1'	System	20 Oct 2020 15:12:01

US3052315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:12:06
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:51

US3052315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:12:06
User entered '9 Oct 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:51

US3052315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:12:06
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:51

US3052315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:12:06
User entered empty.	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:46:51

US3052315

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:12:19
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:12:06

US3052315

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '1'	System	20 Oct 2020 15:12:06

US3052315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:14:50
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 12:22:57

US3052315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:14:50
User entered '16 Oct 2020'	Avia McClain-Stocker (b) (4)	21 Oct 2020 12:22:57

US3052315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:14:50
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 12:22:57

US3052315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:14:50
User entered empty.	Avia McClain-Stocker (b) (4)	21 Oct 2020 12:22:57

US3052315

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:15:17
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:12:11

US3052315

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '1'	System	20 Oct 2020 15:12:11

US3052315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:15:29
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:12:39

US3052315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:15:29
User entered '20 Oct 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:12:39

US3052315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[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 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:15:29
User entered 'Clinic (Clinic)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:12:39

US3052315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'VISIT3'	System	20 Oct 2020 15:12:39

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '20 Oct 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '10:10'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '20 Oct 2020 10:10'	System	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '98.5' F	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered 'Oral (Oral)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered empty.	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '88'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'bpm'	System	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '14'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'breaths/min'	System	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '125'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'mmHg'	System	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:16:29
User entered '85'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'mmHg'	System	20 Oct 2020 15:13:01

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09

US3052315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09

US3052315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:17:07
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:07

US3052315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:17:07
User entered '20 Oct 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:07

US3052315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:17:25
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:22

US3052315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:17:25
User entered '20 Oct 2020'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:22

US3052315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:17:25
User entered '10:23'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:22

US3052315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '20 Oct 2020 10:23'	System	20 Oct 2020 15:13:22

US3052315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:54:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:17:27
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	20 Oct 2020 15:13:25

US3052315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '1'	System	20 Oct 2020 15:13:25

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 64'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-28T14:19:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '351553db-ff21-4587-902d-7846f6429ab4'	System	28 Oct 2020 18:19:11
User entered 'No (N)'	System	28 Oct 2020 18:19:11

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-28T14:19:03', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '351553db-ff21-4587-902d-7846f6429ab4'	System	28 Oct 2020 18:19:11
User entered 'No (N)'	System	28 Oct 2020 18:19:11

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-10-28T14:19:08', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '351553db-ff21-4587-902d-7846f6429ab4' User entered '28 Oct 2020 14:19:08'	System	28 Oct 2020 18:19:11
	System	28 Oct 2020 18:19:11

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 71'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-11-06T13:59:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'd725798a-418f-4914-b6bb-d08e32e49811'	System	06 Nov 2020 18:59:45
User entered 'No (N)'	System	06 Nov 2020 18:59:45

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-11-06T13:59:37', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'd725798a-418f-4914-b6bb-d08e32e49811'	System	06 Nov 2020 18:59:45
User entered 'No (N)'	System	06 Nov 2020 18:59:45

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E9533414-DCC6-4C5A-8837-5BC3638348CE)', Time: '2020-11-06T13:59:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'd725798a-418f-4914-b6bb-d08e32e49811'	System	06 Nov 2020 18:59:45
User entered '06 Nov 2020 13:59:41'	System	06 Nov 2020 18:59:45

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:34
Data entry locked.	System	28 Aug 2020 20:37:50
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00
Data entry locked.	System	28 Aug 2020 20:37:50
User entered 'Day 78'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00
Data entry locked.	System	28 Aug 2020 20:37:50
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 20:37:50

US3052315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:48:00
Data entry locked.	System	28 Aug 2020 20:37:50
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 20:37:50

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:51:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'Yes (Y)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:51:57', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'Yes (Y)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:06', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:11', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'Yes (Y)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '1'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '1'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '1'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:59:24

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:59:24

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:32', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '0'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:36', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'Yes (Y)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:44', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-07T10:52:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '220a9f00-0c2c-41fd-8ef4-46b6ebf12c0c'	System	07 Jan 2021 15:53:06
User entered '07 Jan 2021 10:52:53'	System	07 Jan 2021 15:53:06

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:18:42', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'Yes (Y)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:18:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'Yes (Y)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:18:51', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:07', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'Yes (Y)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '1'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '1'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '1'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '1'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:23', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '0'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:27', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:33', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'Yes (Y)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Please 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-10T02:19:43', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76f68101-743b-4e37-8d48-c55d74b05db9'	System	10 Jan 2021 07:19:53
User entered '10 Jan 2021 02:19:43'	System	10 Jan 2021 07:19:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-17T07:15:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76ff1bbb-1c49-42cf-be3b-bdaf6d7d2fc6'	System	17 Jan 2021 12:15:47
User entered 'No (N)'	System	17 Jan 2021 12:15:47

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-17T07:15:39', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76ff1bbb-1c49-42cf-be3b-bdaf6d7d2fc6'	System	17 Jan 2021 12:15:47
User entered 'No (N)'	System	17 Jan 2021 12:15:47

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-17T07:15:45', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '76ff1bbb-1c49-42cf-be3b-bdaf6d7d2fc6' User entered '17 Jan 2021 07:15:45'	System	17 Jan 2021 12:15:47
	System	17 Jan 2021 12:15:47

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-24T19:46:39', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a1d868cd-67d2-4963-b6e8-e3fe7c493607'	System	25 Jan 2021 00:46:55
User entered 'No (N)'	System	25 Jan 2021 00:46:55

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-24T19:46:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a1d868cd-67d2-4963-b6e8-e3fe7c493607'	System	25 Jan 2021 00:46:55
User entered 'No (N)'	System	25 Jan 2021 00:46:55

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-01-24T19:46:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a1d868cd-67d2-4963-b6e8-e3fe7c493607'	System	25 Jan 2021 00:46:55
User entered '24 Jan 2021 19:46:53'	System	25 Jan 2021 00:46:55

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-02T17:20:50', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '878fbc12-aa85-44b2-b740-d6fdb90b6820'	System	08 Feb 2021 15:09:37
User entered 'No (N)'	System	08 Feb 2021 15:09:37

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-02T17:20:53', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '878fbc12-aa85-44b2-b740-d6fdb90b6820' User entered 'No (N)'	System	08 Feb 2021 15:09:37

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-02T17:20:58', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '878fbc12-aa85-44b2-b740-d6fdb90b6820'	System	08 Feb 2021 15:09:37
User entered '02 Feb 2021 17:20:58'	System	08 Feb 2021 15:09:37

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-08T10:09:38', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01aba58b-cde6-4caf-987e-d06ef315ba12'	System	08 Feb 2021 15:09:53
User entered 'No (N)'	System	08 Feb 2021 15:09:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-08T10:09:41', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01aba58b-cde6-4caf-987e-d06ef315ba12'	System	08 Feb 2021 15:09:53
User entered 'No (N)'	System	08 Feb 2021 15:09:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-08T10:09:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '01aba58b-cde6-4caf-987e-d06ef315ba12'	System	08 Feb 2021 15:09:53
User entered '08 Feb 2021 10:09:49'	System	08 Feb 2021 15:09:53

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-16T12:00:35', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d4f3d1a-e800-4972-a8e6-3f92e36f9ffe'	System	16 Feb 2021 17:04:19
User entered 'No (N)'	System	16 Feb 2021 17:04:19

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-16T12:00:40', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d4f3d1a-e800-4972-a8e6-3f92e36f9ffe'	System	16 Feb 2021 17:04:19
User entered 'No (N)'	System	16 Feb 2021 17:04:19

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-16T12:00:46', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '2d4f3d1a-e800-4972-a8e6-3f92e36f9ffe' User entered '16 Feb 2021 12:00:46'	System	16 Feb 2021 17:04:19
	System	16 Feb 2021 17:04:19

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-21T08:11:49', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '993e4873-a6b2-42cd-b937-337b6d168f38' User entered 'No (N)'	System	21 Feb 2021 13:12:16
	System	21 Feb 2021 13:12:16

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-21T08:11:58', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '993e4873-a6b2-42cd-b937-337b6d168f38'	System	21 Feb 2021 13:12:16
User entered 'No (N)'	System	21 Feb 2021 13:12:16

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-02-21T08:12:14', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '993e4873-a6b2-42cd-b937-337b6d168f38'	System	21 Feb 2021 13:12:16
User entered '21 Feb 2021 08:12:14'	System	21 Feb 2021 13:12:16

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-01T18:52:39-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'bf40c960-e8b0-4bd3-ae1b-5c12ffa56f70'	System	01 Mar 2021 23:52:51
User entered 'No (N)'	System	01 Mar 2021 23:52:51

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-01T18:52:42-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'bf40c960-e8b0-4bd3-ae1b-5c12ffa56f70'	System	01 Mar 2021 23:52:51
User entered 'No (N)'	System	01 Mar 2021 23:52:51

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-01T18:52:46-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'bf40c960-e8b0-4bd3-ae1b-5c12ffa56f70'	System	01 Mar 2021 23:52:51
User entered '01 Mar 2021 18:52:46'	System	01 Mar 2021 23:52:51

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-09T21:21:04-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '401bfd33-c4d8-4d18-8676-0c6b88e56a76'	System	10 Mar 2021 02:29:18
User entered 'No (N)'	System	10 Mar 2021 02:29:18

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-09T21:21:16-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '401bfd33-c4d8-4d18-8676-0c6b88e56a76'	System	10 Mar 2021 02:29:18
User entered 'No (N)'	System	10 Mar 2021 02:29:18

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-09T21:21:20-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '401bfd33-c4d8-4d18-8676-0c6b88e56a76' User entered '09 Mar 2021 21:21:20'	System	10 Mar 2021 02:29:18
	System	10 Mar 2021 02:29:18

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-16T12:30:25-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '03543e13-f634-48ab-87e4-e61113d5cc99'	System	16 Mar 2021 16:30:47
User entered 'No (N)'	System	16 Mar 2021 16:30:47

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-16T12:30:28-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '03543e13-f634-48ab-87e4-e61113d5cc99'	System	16 Mar 2021 16:30:47
User entered 'No (N)'	System	16 Mar 2021 16:30:47

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-16T12:30:34-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '03543e13-f634-48ab-87e4-e61113d5cc99' User entered '16 Mar 2021 12:30:34'	System	16 Mar 2021 16:30:47
	System	16 Mar 2021 16:30:47

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-21T09:07:18-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a366d963-141a-482d-94fa-2d509ae9c167'	System	21 Mar 2021 13:07:26
User entered 'No (N)'	System	21 Mar 2021 13:07:26

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-21T09:07:21-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a366d963-141a-482d-94fa-2d509ae9c167'	System	21 Mar 2021 13:07:26
User entered 'No (N)'	System	21 Mar 2021 13:07:26

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-21T09:07:24-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'a366d963-141a-482d-94fa-2d509ae9c167'	System	21 Mar 2021 13:07:26
User entered '21 Mar 2021 09:07:24'	System	21 Mar 2021 13:07:26

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-30T14:23:30-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '4295fa6b-4ef3-4fb3-ae67-1ecda8aa626c'	System	30 Mar 2021 18:23:41
User entered 'No (N)'	System	30 Mar 2021 18:23:41

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-30T14:23:32-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '4295fa6b-4ef3-4fb3-ae67-1ecda8aa626c'	System	30 Mar 2021 18:23:41
User entered 'No (N)'	System	30 Mar 2021 18:23:41

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-30T14:23:36-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '4295fa6b-4ef3-4fb3-ae67-1ecda8aa626c' User entered '30 Mar 2021 14:23:36'	System	30 Mar 2021 18:23:41
	System	30 Mar 2021 18:23:41

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-07T08:08:31-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '1c8ccd02-123f-4ddc-bf75-16699777e4a9'	System	07 Apr 2021 12:08:40
User entered 'No (N)'	System	07 Apr 2021 12:08:40

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-07T08:08:33-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '1c8ccd02-123f-4ddc-bf75-16699777e4a9'	System	07 Apr 2021 12:08:40
User entered 'No (N)'	System	07 Apr 2021 12:08:40

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-07T08:08:37-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '1c8ccd02-123f-4ddc-bf75-16699777e4a9'	System	07 Apr 2021 12:08:40
User entered '07 Apr 2021 08:08:37'	System	07 Apr 2021 12:08:40

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-11T08:39:05-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'd981389c-921d-48e6-9bd0-29aba17b2a35'	System	11 Apr 2021 12:39:27
User entered 'No (N)'	System	11 Apr 2021 12:39:27

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-11T08:39:07-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'd981389c-921d-48e6-9bd0-29aba17b2a35'	System	11 Apr 2021 12:39:27
User entered 'No (N)'	System	11 Apr 2021 12:39:27

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-11T08:39:25-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: 'd981389c-921d-48e6-9bd0-29aba17b2a35'	System	11 Apr 2021 12:39:27
User entered '11 Apr 2021 08:39:25'	System	11 Apr 2021 12:39:27

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-18T06:03:52-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '64a017c2-a39c-4444-a3b6-1074f930bcd2'	System	18 Apr 2021 11:04:04
User entered 'No (N)'	System	18 Apr 2021 11:04:04

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-18T06:03:58-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '64a017c2-a39c-4444-a3b6-1074f930bcd2'	System	18 Apr 2021 11:04:04
User entered 'No (N)'	System	18 Apr 2021 11:04:04

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-18T06:04:02-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '64a017c2-a39c-4444-a3b6-1074f930bcd2' User entered '18 Apr 2021 06:04:02'	System	18 Apr 2021 11:04:04
	System	18 Apr 2021 11:04:04

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-25T00:24:39-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '4a9270db-6a3e-43f8-a26c-aaca830612ee'	System	25 Apr 2021 04:24:51
User entered 'No (N)'	System	25 Apr 2021 04:24:51

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

Have you been exposed to someone with 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 (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-25T00:24:41-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '4a9270db-6a3e-43f8-a26c-aaca830612ee'	System	25 Apr 2021 04:24:51
User entered 'No (N)'	System	25 Apr 2021 04:24:51

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-04-25T00:24:47-04:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '4a9270db-6a3e-43f8-a26c-aaca830612ee'	System	25 Apr 2021 04:24:51
User entered '25 Apr 2021 00:24:47'	System	25 Apr 2021 04:24:51

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:48:00

US3052315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:00
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:48:00

US3052315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:59:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-01T18:52:53-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '060a0e73-1591-4e2d-ae42-698a3631ba88'	System	01 Mar 2021 23:53:00
User entered 'No (N)'	System	01 Mar 2021 23:53:00

US3052315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:59:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCA57EBD-1C05-4646-BF7A-1126BCA5CE07)', Time: '2021-03-01T18:52:57-05:00', User OID: 'PatientReportedOutcome (US3052315)', ODM File OID: '060a0e73-1591-4e2d-ae42-698a3631ba88'	System	01 Mar 2021 23:53:00
User entered '01 Mar 2021 18:52:57'	System	01 Mar 2021 23:53:00

US3052315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
DataPoint Verified.		16 Apr 2021 18:08:02
User closed query 'Please provide source.' (Site from CRA).		16 Apr 2021 18:07:58
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:55
Query 'Please provide source.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:29
Signature has been broken.		14 Apr 2021 18:56:17
User entered 'No (N)' reason for change: Data Entry Error		14 Apr 2021 18:56:17
User opened query 'Please provide source.' (Site from CRA).		06 Apr 2021 16:32:56
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:15:29

US3052315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
DataPoint Verified.		16 Apr 2021 18:08:02
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:17
User entered empty; reason for change Data Entry Error		14 Apr 2021 18:56:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:15:29

US3052315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
DataPoint Verified.		16 Apr 2021 18:08:02
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:17
User entered empty; reason for change Data Entry Error		14 Apr 2021 18:56:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:15:29

US3052315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
DataPoint Verified.	(b) (4)	16 Apr 2021 18:08:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:15:29

US3052315

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
DataPoint Verified.		06 Apr 2021 16:33:18
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:22:22

US3052315

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	22 Dec 2020 21:22:22

US3052315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		08 Apr 2021 20:40:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:22:47

US3052315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		08 Apr 2021 20:40:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 27JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 07:31:26
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 27JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:20:41
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 27JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).		03 Feb 2021 12:24:44
User entered '22 Dec 2020'		22 Dec 2020 21:22:47

US3052315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		08 Apr 2021 20:40:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:22:47

US3052315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:40:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Left VM'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:22:47

US3052315

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		06 Apr 2021 16:31:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 07:38:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'updated. also please advise as to the repeated identical queries' (Site from DM).		04 Mar 2021 16:22:46
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).		01 Mar 2021 08:04:51
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	04 Jan 2021 01:18:43

US3052315

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
User entered '1'	System	04 Jan 2021 01:18:43

US3052315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		08 Apr 2021 20:40:32
Query 'Please provide source.' canceled (Site from CRA).		08 Apr 2021 20:40:30
User opened query 'Please provide source.' (Site from CRA).		06 Apr 2021 16:34:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:16:30

US3052315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		08 Apr 2021 20:40:32
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
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 07:37:39
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).		14 Feb 2021 02:16:45
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 02:16:30
User entered '08 Feb 2021'	(b) (4), (b) (6)	14 Feb 2021 02:16:30

US3052315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:40:32
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:16:30

US3052315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:40:32
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:16:30

US3052315

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:34:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:15:43

US3052315

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
User entered 'I'	System	15 Mar 2021 13:15:43

US3052315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		16 Apr 2021 18:08:13
User closed query 'Please provide source.' (Site from CRA).		16 Apr 2021 18:08:12
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:55
Query 'Please provide source.' answered with 'not done' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:46
Signature has been broken.		14 Apr 2021 18:35:24
User entered 'No (N)' reason for change: Data Entry Error		14 Apr 2021 18:35:24
User opened query 'Please provide source.' (Site from CRA).		06 Apr 2021 16:35:10
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:16:08

US3052315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		16 Apr 2021 18:08:13
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:24
User entered empty; reason for change Data Entry Error		14 Apr 2021 18:35:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:16:08

US3052315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:08:13
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:24
User entered empty; reason for change Data Entry Error		14 Apr 2021 18:35:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:16:08

US3052315

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:08:13
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:16:08

US3052315

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
DataPoint Verified.		06 Apr 2021 16:35:13
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:16:14

US3052315

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:52:18
User entered 'I'	System	15 Mar 2021 13:16:14

US3052315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:40
User entered 'Yes (Y)'		24 Mar 2021 14:41:34

US3052315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:40
User entered '22 Mar 2021'		24 Mar 2021 14:41:34

US3052315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[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 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:40
User entered 'Clinic (Clinic)'		24 Mar 2021 14:41:34

US3052315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered 'VISIT4'	System	24 Mar 2021 14:41:34

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered 'Yes (Y)'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '22 Mar 2021'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '11:25'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered '22 Mar 2021 11:25'	System	31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '98.9' F		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered 'Oral (Oral)'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered empty.		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '94'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered 'bpm'	System	31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '17'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered 'breaths/min'	System	31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '128'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered 'mmHg'	System	31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:29:53
User entered '84'		31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered 'mmHg'	System	31 Mar 2021 14:14:51

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27

US3052315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27

US3052315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:30:16
User entered 'Yes (Y)'		24 Mar 2021 14:41:44

US3052315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:30:16
User entered '22 Mar 2021'		24 Mar 2021 14:41:44

US3052315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:30:23
User entered 'Yes (Y)'		24 Mar 2021 14:42:13

US3052315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:30:23
User entered '22 Mar 2021'		24 Mar 2021 14:42:13

US3052315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:30:23
User entered '12:07'		24 Mar 2021 14:42:13

US3052315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered '22 Mar 2021 12:07'	System	24 Mar 2021 14:42:13

US3052315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:30:26
User entered 'Yes (Y)'		26 Mar 2021 19:51:50

US3052315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:27
User entered '1'	System	26 Mar 2021 19:51:50

US3052315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:45:32

US3052315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:45:32

US3052315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:45:32

US3052315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:45:32

US3052315

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:45:37

US3052315

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 12:45:37

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:40
DataPoint Verified.		03 May 2021 12:34:35
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:52:49

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:40
DataPoint Verified.		03 May 2021 12:34:35
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered '11:00'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:52:49

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:40
User entered '14 Jan 2021 11:00'	System	30 Apr 2021 12:52:49

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:40
DataPoint Verified.		03 May 2021 12:34:35
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:52:49

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:40
DataPoint Verified.		03 May 2021 12:34:35
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:52:49

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.		03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	30 Apr 2021 12:55:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 12:55:47
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 12:55:47
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:55:40
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.		03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
User entered empty.	System	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:39
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:40

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:34:43
User signature succeeded.	Yaa Oppong (b) (4)	30 Apr 2021 19:53:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:07:00
User entered '0'	System	30 Apr 2021 12:56:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:04
User closed query 'Per CDM RQ: Site response noted. Please note that per Narrative on AE#1 " SUBJECT INFORMED SITE OF HOSPITAL ADMISSION AND DIAGNOSIS 12:52 ON 06 DEC 2020." Please note that the date recorded here is 22 DEC 2020. Kindly review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:16:37
Query 'Per CDM RQ: Site response noted. Please note that per Narrative on AE#1 " SUBJECT INFORMED SITE OF HOSPITAL ADMISSION AND DIAGNOSIS 12:52 ON 06 DEC 2020." Please note that the date recorded here is 22 DEC 2020. Kindly review and reconcile, else clarify. ' answered with 'patient was hospitalized due to Covid. notification made by the patient to staff during a safety call placed 12/22/2020. site was not notified until 12/22/2020' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 14:11:05
User opened query 'Per CDM RQ: Site response noted. Please note that per Narrative on AE#1 " SUBJECT INFORMED SITE OF HOSPITAL ADMISSION AND DIAGNOSIS 12:52 ON 06 DEC 2020." Please note that the date recorded here is 22 DEC 2020. Kindly review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:12:15
User closed query 'Per CDM: The Date of Contact is 22Dec2020, however, the Date of Visit and the Date of Test on the COVID Diagnostic Test form in this Covid-19 Assessment folder are 14Jan2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:12:15
Query 'Per CDM: The Date of Contact is 22Dec2020, however, the Date of Visit and the Date of Test on the COVID Diagnostic Test form in this Covid-19 Assessment folder are 14Jan2021. Please review and reconcile.' answered with 'confirmed subject was not seen until 14 JAN. Subject was in Hospital 22 DEC 2020' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:48:52

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: The Date of Contact is 22Dec2020, however, the Date of Visit and the Date of Test on the COVID Diagnostic Test form in this Covid-19 Assessment folder are 14Jan2021. Please review and reconcile.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:44:00
	(b) (4), (b) (6)	06 Apr 2021 16:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
	(b) (4)	
User closed query 'Per ETRTR: Please complete data entry within COVID Diagnostic Test and Severity Assessment page, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 20:45:50
Query 'Per ETRTR: Please complete data entry within COVID Diagnostic Test and Severity Assessment page, thanks.' answered with 'updated' (Site from CRA).	Stacey Saldua (b) (4)	27 Jan 2021 20:54:11
	(b) (4)	
User opened query 'Per ETRTR: Please complete data entry within COVID Diagnostic Test and Severity Assessment page, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 23:33:59
User entered '22 Dec 2020'	Stacey Saldua (b) (4)	22 Dec 2020 21:32:13
	(b) (4)	

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:04
DataPoint Verified.		06 Apr 2021 16:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '12:52'	(b) (4) Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:32:13

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:04
User entered '22 Dec 2020 12:52'	System	22 Dec 2020 21:32:13

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:04
DataPoint Verified.	(b) (4)	06 Apr 2021 16:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Safety Call (Safety Call)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:32:13

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:04
DataPoint Verified.	(b) (4)	06 Apr 2021 16:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:32:13

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
User closed query 'Per CDM: Only Day 28 is listed on the Symptom Log. Please provide responses for days prior to day 28.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:51:08
Query 'Per CDM: Only Day 28 is listed on the Symptom Log. Please provide responses for days prior to day 28.' answered with 'only symptoms recorded were in clinic at day 28 convalescent visit' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:53:40
User opened query 'Per CDM: Only Day 28 is listed on the Symptom Log. Please provide responses for days prior to day 28.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:45:48
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User entered 'Day 28 (Day 28)'	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.		06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.		06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '97'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
User entered '%'	System	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.0' F	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Moderate (Moderate)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Moderate (Moderate)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Moderate (Moderate)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Moderate (Moderate)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:49:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'None (None)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:23:17

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:34:33
User entered '22 Dec 2020' reason for change: Data Entry Error		03 May 2021 20:33:20
DataPoint Un-verified.		03 May 2021 20:17:56
User entered '09 Dec 2020' reason for change: Data Entry Error		03 May 2021 20:17:56
DataPoint Verified.		03 May 2021 18:58:54
DataPoint Un-verified.		03 May 2021 18:40:28
Signature has been broken.		03 May 2021 18:40:28
User entered '22 Dec 2020' reason for change: Data Entry Error		03 May 2021 18:40:28
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 13:24:12
DataPoint Un-verified.		03 May 2021 12:41:33
Signature has been broken.		03 May 2021 12:41:33
User entered '09 Dec 2020' reason for change: Data Entry Error		03 May 2021 12:41:33
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:29:50

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 21:30:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 21:30:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:30:17
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 21:29:50
User entered empty.	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:29:50

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:59:00
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'covid 19 is already on the AE page' (Site from System).		03 May 2021 18:41:34
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 May 2021 18:40:28
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 18:40:28
User entered 'Yes (Y)' reason for change: Data Entry Error		03 May 2021 18:40:28
DataPoint Un-verified.		03 May 2021 16:04:28
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
User closed query 'Please verify and consider updating to the local lab results that were positive when subject was hospitalized.' (Site from CRA).		29 Apr 2021 20:25:39
Query 'Please verify and consider updating to the local lab results that were positive when subject was hospitalized.' answered with 'According to the results report for this illness visit, COVID was not detected.' (Site from CRA).		23 Apr 2021 20:01:52
User opened query 'Please verify and consider updating to the local lab results that were positive when subject was hospitalized.' (Site from CRA).		22 Apr 2021 22:11:08
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User closed query ' Per CDM: The AE form has 'COVID-19' with a start date of 14Jan2021 and 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes but Did the subject test positive for SARS-COV-2 by RT-PCR is blank. Please review and reconcile, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 11:14:02

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:09:34
Query 'Per CDM: The AE form has 'COVID-19' with a start date of 14Jan2021 and 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes but Did the subject test positive for SARS-COV-2 by RT-PCR is blank. Please review and reconcile, else clarify.' answered with 'subject tested positive 06 DEC 2020 but was not tested in clinic until 14 jan 2021' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:53:09
DataPoint Un-verified.	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:53:04
Signature has been broken.	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:53:04
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:53:04
User opened query 'Per CDM: The AE form has 'COVID-19' with a start date of 14Jan2021 and 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes but Did the subject test positive for SARS-COV-2 by RT-PCR is blank. Please review and reconcile, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:49:56
Query 'Per CDM: Please provide a response.' canceled (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:49:25
User opened query 'Per CDM: Please provide a response.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:48:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 07:45:46
Query 'Data is required. Please complete.' answered with 'will confirm when ppd obtains the results ' (Site from System).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:34:34
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 21:34:05
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	27 Jan 2021 21:34:05

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered by data change (Site from System).	System	27 Jan 2021 21:34:05
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 21:34:05
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 21:30:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 21:30:17
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	27 Jan 2021 21:30:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 21:30:17
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 21:29:50
User entered empty.	Stacey Saldua (b) (4)	27 Jan 2021 21:29:50

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:21:01
User entered '09 Dec 2020' reason for change: Data Entry Error		03 May 2021 20:17:56
DataPoint Un-verified.		03 May 2021 18:40:28
Signature has been broken.		03 May 2021 18:40:28
User entered '22 Dec 2020' reason for change: Data Entry Error		03 May 2021 18:40:28
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 17:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 13:24:12
DataPoint Un-verified.		03 May 2021 12:41:33
Signature has been broken.		03 May 2021 12:41:33
User entered '09 Dec 2020' reason for change: Data Entry Error		03 May 2021 12:41:33
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).		16 Apr 2021 04:33:31
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' answered with 'subject tested positive outside of clinic on 06 dec 2020 but was tested in clinic 14 jan 2021' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:52:56
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:38

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	24 Mar 2021 09:53:26
User closed query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:58:20
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:39:21
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:34:49
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:29:18
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:29:11

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'illness visit added' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:24:03
User opened query 'Per CDM: A diagnostic test has been completed, however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:44:51
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 08:47:34
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 08:47:23
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 08:44:56
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 08:44:44

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 14 JAN 2021 is reported under illness Visit Day 1 in PPD, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 07:37:03
Query 'Per Lab Recon: SARS-COV2: There seems to be a data entry error, in regards to the year in this date of test. Please check and update if it should be "14 JAN 2021" instead of "2020". Thank you.' canceled (Site from DM).		25 Feb 2021 07:36:35
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).		05 Feb 2021 09:03:18
User opened query 'Per Lab Recon: SARS-COV2: There seems to be a data entry error, in regards to the year in this date of test. Please check and update if it should be "14 JAN 2021" instead of "2020". Thank you.' (Site from DM).		28 Jan 2021 07:53:11
Query 'The Date of Test is before the Date of Informed Consent. Please review and reconcile.' canceled (Site from System).		28 Jan 2021 07:51:33
User opened query 'The Date of Test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	27 Jan 2021 21:31:37
User entered '14 Jan 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 21:31:37
User entered '2 Dec 2020'	(b) (4)	
	Stacey Saldua (b) (4)	27 Jan 2021 21:29:50
	(b) (4)	

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
DataPoint Verified.		06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:31:37
User entered 'Other (Other)'	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:29:50

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Folder: Covid-19 Assessment 22 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
DataPoint Verified.		06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:31:37
User entered 'Patient got tested 12/2/2020 at local hospital. Patient received results on 12/6/2020 patient tested Positive. Patient was admitted to the hospital 12/9/2020-12/18/2020'	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:29:50

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:53:59
Signature has been broken.		03 May 2021 18:40:28
User entered 'Yes (Y)' reason for change: Data Entry Error		03 May 2021 18:40:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 16:04:24
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
User closed query 'Please verify and consider updating to the local lab results that were positive when subject was hospitalized. This field and the following two fields should be updated' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 20:25:42
Query 'Please verify and consider updating to the local lab results that were positive when subject was hospitalized. This field and the following two fields should be updated' answered with 'According to the results report for this illness visit, COVID was not detected.' (Site from CRA).		23 Apr 2021 20:01:55
User opened query 'Please verify and consider updating to the local lab results that were positive when subject was hospitalized. This field and the following two fields should be updated' (Site from CRA).		22 Apr 2021 22:11:39
DataPoint Verified.		06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:31:37
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:29:50
	(b) (4)	

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:54:01
User closed query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 18:42:05
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 18:42:05
Signature has been broken.		03 May 2021 18:42:05
User entered 'First Health of the carolinas' reason for change: Data Entry Error		03 May 2021 18:42:05
User opened query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 18:40:28
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty; reason for change Data Entry Error	(b) (4) Stacey Saldua (b) (4)	27 Jan 2021 21:31:37
User entered 'Moore Regional hospital'	Stacey Saldua (b) (4)	27 Jan 2021 21:29:50
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:54:02
User closed query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 18:42:05
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 18:42:05
Signature has been broken.		03 May 2021 18:42:05
User entered 'Yes (Y)' reason for change: Data Entry Error		03 May 2021 18:42:05
User opened query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 18:40:28
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:56:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:38
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty; reason for change Data Entry Error	(b) (4)	27 Jan 2021 21:31:37
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 21:29:50

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:40:28
Data hard unlocked.	KC Joubran (b) (4)	30 Apr 2021 20:21:06
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 13:56:38
User entered '0'	System	13 Apr 2021 19:53:04
User entered '1'	System	27 Jan 2021 21:30:17

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Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'Yes (Y)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered '09 Dec 2020'		03 May 2021 20:16:51

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'Yes (Y)'		03 May 2021 20:16:51

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered '09 Dec 2020'		03 May 2021 20:16:51

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered '18 Dec 2020'		03 May 2021 20:16:51

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'Yes (Y)'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered '09 Dec 2020'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 20:19:16
User entered 'No (N)'		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:24

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:46
User signature succeeded.	Yaa Oppong (b) (4)	03 May 2021 23:22:07
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:16
User entered empty.		03 May 2021 20:16:51

US3052315

Folder: Covid-19 Assessment 22 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:59:24

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	04 May 2021 00:29:29
Data hard locked.		29 Apr 2021 18:49:31
DataPoint Verified.		06 Apr 2021 16:49:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:58:32

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 5 (Day 5)'		04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:59:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:59:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:57:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:37:04

US3052315

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:08
User closed query 'If Illness visit was not completed then the data needs to reflect visit was not performed and data below removed. ' (Site from CRA).		20 Apr 2021 16:25:06
Query 'If Illness visit was not completed then the data needs to reflect visit was not performed and data below removed. ' answered with 'updated' (Site from CRA).		20 Apr 2021 15:55:23
Signature has been broken.		20 Apr 2021 15:55:19
User entered 'No (N)' reason for change: Data Entry Error		20 Apr 2021 15:55:19
User opened query 'If Illness visit was not completed then the data needs to reflect visit was not performed and data below removed. ' (Site from CRA).		16 Apr 2021 18:15:19
User closed query 'Please review visit date. Illness visit day is same date as Convalescence period Day 28. ' (Site from CRA).		16 Apr 2021 18:15:19
Query 'Please review visit date. Illness visit day is same date as Convalescence period Day 28. ' answered with 'Visit 1 was not conducted. Only a convalescence Day 28 was conducted after subject was in hospital' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:44:50
User opened query 'Please review visit date. Illness visit day is same date as Convalescence period Day 28. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:00:44
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	(b) (4) System	04 Mar 2021 16:26:36
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	04 Mar 2021 16:26:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 16:26:23
User entered 'No (N)'		04 Mar 2021 15:32:53

US3052315

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:08
Signature has been broken.		20 Apr 2021 15:55:19
User entered empty; reason for change Data Entry Error		20 Apr 2021 15:55:19
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:26:36
User entered empty.		04 Mar 2021 15:32:53

US3052315

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[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 21:31:20
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:08
Signature has been broken.		20 Apr 2021 15:55:19
User entered empty; reason for change Data Entry Error		20 Apr 2021 15:55:19
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4) System	04 Mar 2021 16:26:36
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 16:26:36
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	04 Mar 2021 16:26:23
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 15:32:53

US3052315

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User entered 'SICKD1'	System	04 Mar 2021 15:32:53

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User entered empty.	System	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User entered empty.	System	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User entered empty.	System	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:24
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User entered empty.	System	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Signature has been broken indirectly.	(b) (4)	20 Apr 2021 15:55:19
DataPoint Verified.	System	16 Apr 2021 18:12:24
	(b) (4), (b) (6)	
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User entered empty.	System	04 Mar 2021 16:28:08

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20

US3052315

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20

US3052315

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:13

US3052315

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:12:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:28:13

US3052315

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:24

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 06:09:16
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:41:55
User closed query 'Data should be removed as per answer to query on visit date the illness visit did not occur.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:41:52
Query 'Data is required. Please complete.' answered with 'data was removed per query resolution' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 15:54:28
Query 'Data should be removed as per answer to query on visit date the illness visit did not occur.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 15:54:07
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:54:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:54:07
User opened query 'Data should be removed as per answer to query on visit date the illness visit did not occur.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:15:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2: Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? is "NO", However Date of collection is present, please review and update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 07:03:34
Query ' Per GCL Lab Reconciliation: SARS-CoV-2: Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? is "NO", However Date of collection is present, please review and update as needed. ' answered with 'Updated ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 19:24:55

US3052315

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:24

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 19:24:41
User entered 'Yes (Y)' reason for change: Data Entry Error		23 Mar 2021 19:24:41
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2: Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? is "NO", However Date of collection is present, please review and update as needed. ' (Site from DM).		22 Mar 2021 08:25:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:09:47
User entered 'Yes (Y)'		04 Mar 2021 16:28:32

US3052315

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:31:20
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:41:55
Signature has been broken.		20 Apr 2021 15:54:07
User entered empty; reason for change Data Entry Error		20 Apr 2021 15:54:07
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:02:03
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:09:45
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' (Site from DM).		09 Mar 2021 03:57:28
User entered '14 Jan 2021'		04 Mar 2021 16:28:32

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.		16 Apr 2021 18:16:19
User closed query 'Please review visit date. Illness visit day is same date. Illness visit is Day 1 and This visit should be 28 days later.' (Site from CRA).		16 Apr 2021 18:16:17
Query 'Please review visit date. Illness visit day is same date. Illness visit is Day 1 and This visit should be 28 days later.' answered with 'Illness day one was not performed. Only Day 28 after subject was discharged from hospital' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:46:30
User opened query 'Please review visit date. Illness visit day is same date. Illness visit is Day 1 and This visit should be 28 days later.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:00:09
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 15:33:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4)	16 Apr 2021 18:16:19
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:33:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:19
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:33:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'SICKD28'	System	04 Mar 2021 15:33:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '11:20'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered '14 Jan 2021 11:20'	System	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55
DataPoint set to visible.	System	04 Mar 2021 15:33:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55
DataPoint set to visible.	System	04 Mar 2021 15:33:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '95'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'bpm'	System	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '18'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'breaths/min'	System	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '128'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'mmHg'	System	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:28
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '82'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'mmHg'	System	04 Mar 2021 15:34:55

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:32
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:35:25

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:32
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:35:25

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:24

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:36:27

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2:RQ: Response is not clear, Still there is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1). However, as per the Preclarus SARS sample dated 14 JAN 2021 is collected for the illness visit Day1. Please review for which visit (i.e., illness or Convalescent)the sars sample is collected then remove duplicate sample and update appropriately else please clarify the reason for the duplicate entry of the sample in EDC.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:46:24
Query 'Per GCL Lab Reconciliation: SARS-CoV-2:RQ: Response is not clear, Still there is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1). However, as per the Preclarus SARS sample dated 14 JAN 2021 is collected for the illness visit Day1. Please review for which visit (i.e., illness or Convalescent)the sars sample is collected then remove duplicate sample and update appropriately else please clarify the reason for the duplicate entry of the sample in EDC.' answered with 'Convalescent' (Site from DM).	Avia McClain-Stocker (b) (4)	16 Apr 2021 18:17:20
Query 'Per GCL Lab Reconciliation: SARS-CoV-2:RQ: Response is not clear, Still there is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1). However, as per the Preclarus SARS sample dated 14 JAN 2021 is collected for the illness visit Day1. Please review for which visit (i.e., illness or Convalescent)the sars sample is collected then remove duplicate sample and update appropriately else please clarify the reason for the duplicate entry of the sample in EDC.' answered with 'Convalescent' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:46:54
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:36:26

US3052315

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:24

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2:RQ: Response is not clear, Still there is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1). However, as per the Preclarus SARS sample dated 14 JAN 2021 is collected for the illness visit Day1. Please review for which visit (i.e., illness or Convalescent)the sars sample is collected then remove duplicate sample and update appropriately else please clarify the reason for the duplicate entry of the sample in EDC.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:36:21
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' answered with 'completed on the same day from edc' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 17:53:33
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: There is a duplicate entry for the SARS-CoV-2 sample dated 14 JAN 2021 as it is recorded under Convalescence Visit Day 28 and illness Visit Day1 in EDC for illness Visit (1), Please review and update appropriately.' (Site from DM).		24 Mar 2021 07:04:05
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:36:27

US3052315

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:48

US3052315

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:48

US3052315

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:48

US3052315

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 15:50:48

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:42:50
User entered '0'		24 Mar 2021 14:40:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:18:13

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:42:50
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	24 Mar 2021 14:40:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:18:13

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:42:50
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1'	System	04 Mar 2021 15:57:58

US3052315

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1'	System	04 Mar 2021 15:57:58

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '182.88' cm	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:18:37
User closed query 'Per source, weight is 94.8. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:18:35
Query 'Per source, weight is 94.8. Please review and reconcile.' answered with 'updated' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:52
Signature has been broken.	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:47
User entered '94.8' kg reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:07
DataPoint Verified.		06 Apr 2021 16:44:06
User opened query 'Per source, weight is 94.8. Please review and reconcile.' (Site from CRA).		06 Apr 2021 16:43:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.8' kg	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '28.34496'	System	13 Apr 2021 19:39:47
User entered '29.54095'	System	04 Mar 2021 16:01:10
DataPoint set to visible.	System	04 Mar 2021 15:57:58

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '182.88' cm	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:18:37
User closed query 'Per source, weight is 94.8. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:18:35
Query 'Per source, weight is 94.8. Please review and reconcile.' answered with 'updated' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:52
Signature has been broken.	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:47
User entered '94.8' kg reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User opened query 'Per source, weight is 94.8. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:43:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.8' kg	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '28.34496'	System	13 Apr 2021 19:39:47
User entered '29.54095'	System	04 Mar 2021 16:01:10
DataPoint set to visible.	System	04 Mar 2021 15:57:58

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '12:39'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '27 Jan 2021 12:39'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '94'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'bpm'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '15'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'breaths/min'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '130'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '92'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '182.88' cm	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	19 Apr 2021 02:32:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:18:37
User closed query 'Per source, weight is 94.8. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:18:35
Query 'Per source, weight is 94.8. Please review and reconcile.' answered with 'updated' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:52
Signature has been broken.	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:47
User entered '94.8' kg reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:39:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User opened query 'Per source, weight is 94.8. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:43:39
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.8' kg	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '28.34496'	System	13 Apr 2021 19:39:47
User entered '29.54095'	System	04 Mar 2021 16:01:10
DataPoint set to visible.	System	04 Mar 2021 15:57:58

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14:57'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '27 Jan 2021 14:57'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '90'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'bpm'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'breaths/min'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '127'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:06
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '87'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:10

US3052315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:01:10

US3052315

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:43

US3052315

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:40
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:01:43

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mRNA-1273'	System	04 Mar 2021 16:02:13
DataPoint set to visible.	System	04 Mar 2021 15:57:58

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '14:20'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '27 Jan 2021 14:20'	System	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:44:54
User entered 'ONCE'	System	04 Mar 2021 16:02:13

US3052315

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

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 16:02:13

US3052315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:14
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:42

US3052315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:14
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:42

US3052315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:14
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '13:36'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:02:42

US3052315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '27 Jan 2021 13:36'	System	04 Mar 2021 16:02:42

US3052315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:03:11

US3052315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:03:11

US3052315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '13:38'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:03:11

US3052315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '27 Jan 2021 13:38'	System	04 Mar 2021 16:03:11

US3052315

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

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:45:20
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:03:24

US3052315

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

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1'	System	04 Mar 2021 16:03:24

US3052315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:41:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	15 Mar 2021 23:50:52
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	15 Mar 2021 13:14:50
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 13:14:50

US3052315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:41:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:14:50

US3052315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:41:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	amy sheets (b) (4)	15 Mar 2021 23:50:52
	(b) (4)	
	(b) (4), (b) (6)	15 Mar 2021 13:14:50

US3052315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:41:08
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'missed'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:14:50

US3052315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:41:11
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:11:53

US3052315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'I'	System	04 Mar 2021 16:11:53

US3052315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1'	System	04 Mar 2021 16:11:53
DataPoint set to visible.	System	04 Mar 2021 16:11:53

US3052315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:12:37

US3052315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:12:37

US3052315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:12:37

US3052315

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'OLD29'	System	04 Mar 2021 16:12:37

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User accepted default value 'Pre-Dose (PREDOSE)'		04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '11:30'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1 Mar 2021 11:30'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '37.2' C	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '82'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'bpm'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '15'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'breaths/min'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '130'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '80'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '12:38'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1 Mar 2021 12:38'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '76'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'bpm'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '15'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'breaths/min'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '147'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:37
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '92'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	04 Mar 2021 16:18:51

US3052315

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:59

US3052315

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:39:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:18:59

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mRNA-1273'	System	04 Mar 2021 16:19:18
DataPoint set to visible.	System	04 Mar 2021 16:11:53

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '12:05'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1 Mar 2021 12:05'	System	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:02
User entered 'ONCE'	System	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 16:19:18

US3052315

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:07
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:19:24

US3052315

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '1'	System	04 Mar 2021 16:19:24

US3052315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	15 Mar 2021 23:50:37
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	15 Mar 2021 13:14:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:14:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 13:13:49

US3052315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 13:14:24
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	15 Mar 2021 13:14:24
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	15 Mar 2021 13:14:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:14:24
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 13:13:49
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	15 Mar 2021 13:13:49
User entered '23 Nov 2020'	(b) (4), (b) (6)	15 Mar 2021 13:13:49

US3052315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty; reason for change Data Entry Error	(b) (4)	
	amy sheets (b) (4)	15 Mar 2021 23:50:37
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	15 Mar 2021 13:14:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Mar 2021 13:13:49

US3052315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:40:41
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'missed' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	15 Mar 2021 13:14:24
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 13:13:49

US3052315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:40:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:42:27

US3052315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'I'	System	24 Mar 2021 14:42:27

US3052315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:35:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:42:39

US3052315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:35:39
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 18:29:11
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Date confirmed' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 14:43:27
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 14:42:39
User entered '22 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:42:39

US3052315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:35:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 14:42:39

US3052315

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'OLD57'	System	24 Mar 2021 14:42:39

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '22 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '11:25'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '22 Mar 2021 11:25'	System	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '98.9' F	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '94'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'bpm'	System	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '17'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'breaths/min'	System	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '128'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:52
User entered '84'	(b) (4), (b) (6)	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered 'mmHg'	System	24 Mar 2021 14:44:26

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13

US3052315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13

US3052315

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:44:49

US3052315

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:56
User entered '22 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:44:49

US3052315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:45:15

US3052315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:59
User entered '22 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:45:15

US3052315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:36:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:59
User entered '12:07'	(b) (4), (b) (6)	24 Mar 2021 14:45:15

US3052315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:13
User entered '22 Mar 2021 12:07'	System	24 Mar 2021 14:45:15

US3052315

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:59:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:19:07
User closed query 'Per CDM CLR Re-query: Per response update in AE however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 09:54:07
Query 'Per CDM CLR Re-query: Per response update in AE however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' answered with 'diary entry is in regards to AE line already existing. nothing newer than that' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:56:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:25
User opened query 'Per CDM CLR Re-query: Per response update in AE however there is no change reflecting in the eCRF, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 15:56:39
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 131 & 138, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 15:55:21
Query 'Per DM CLR: Per Safety Follow Up Diary Day 131 & 138, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'updated in ae' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 17:54:42

US3052315

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:59:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 131 & 138, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	25 Mar 2021 01:46:55
	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)' reason for change: New Information	Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:21:22
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 19:47:08

US3052315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:43
User entered 'USA-US117-2020-mRNA-1273-P301000005'	System	23 Dec 2020 13:52:37
User entered 'New'	(b) (4), (b) (6)	23 Dec 2020 13:52:37

US3052315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per sponsor review, please update term to Covid-19 or Symptomatic Covid-19 per CCGs pg 45' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:26:56
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 18:17:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 18:17:16
Data point term sent to Coder	System	27 Jan 2021 18:16:22
Query 'Per sponsor review, please update term to Covid-19 or Symptomatic Covid-19 per CCGs pg 45' answered with 'updated' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 18:15:57
Coding entries removed.	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 18:15:48
User entered 'COVID-19' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 18:15:48
User opened query 'Per sponsor review, please update term to Covid-19 or Symptomatic Covid-19 per CCGs pg 45' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 13:43:54
DataPoint Un-verified.		29 Dec 2020 17:37:53
DataPoint Verified.		29 Dec 2020 17:37:51
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:18:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:18:42
Data point term sent to Coder	System	22 Dec 2020 21:27:02
User entered 'COVID-19 Hospitalization'	Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:26:25

US3052315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
	(b) (4)	
User entered '27 Nov 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4)	22 Dec 2020 21:27:13
	(b) (4)	
User entered '11 Nov 2020'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	27 Jan 2021 18:19:59
User entered empty; reason for change Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 18:19:59
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Dec 2020 21:26:25
User entered '8:00'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 18:19:59
User entered '27 Nov 2020 8:00'	System	22 Dec 2020 21:27:13
User entered '11 Nov 2020 8:00'	System	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	27 Jan 2021 20:46:57
User entered 'No (N)' reason for change: Data Entry Error	System	27 Jan 2021 20:46:57
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Stacey Saldua (b) (4)	27 Jan 2021 20:46:57
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 20:42:41
	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:50:06
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 15:03:54
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'update' (Site from System).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:43:15
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'confirmed' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:42:50
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Jan 2021 20:42:41
User entered '18 Dec 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:42:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:09:14
User entered empty.	Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:26:25

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '9 Dec 2020'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'PV Query: Per discharge summary and case narrative, the subject was discharged 18Dec2020. Please reconcile and update the discharge date.' (Site from Safety).	(b) (4)	28 Jan 2021 15:04:09
Query 'PV Query: Per discharge summary and case narrative, the subject was discharged 18Dec2020. Please reconcile and update the discharge date.'	Stacey Saldua (b) (4)	27 Jan 2021 20:43:32
answered with 'updated' (Site from Safety).	(b) (4)	
User entered '18 Dec 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 18:19:59
User opened query 'PV Query: Per discharge summary and case narrative, the subject was discharged 18Dec2020. Please reconcile and update the discharge date.' (Site from Safety).	(b) (4)	31 Dec 2020 14:11:59
User entered '12 Dec 2020'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	27 Jan 2021 20:44:55
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	27 Jan 2021 20:44:55
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 20:44:55
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	22 Dec 2020 21:26:25
User entered 'Unknown (UNK)'	System	22 Dec 2020 21:26:25
	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' (Site from Safety).	(b) (4)	05 Mar 2021 18:18:50
Query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:30:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:29:41
User opened query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:57:17
User closed query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 15:04:14
Query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' answered with 'Updated' (Site from Safety).	Stacey Saldua (b) (4)	27 Jan 2021 20:45:15
User opened query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: As the subject had received both doses of study drug please update causality for the study drug from not applicable to Related or Not Related.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:08:16
User entered 'Not Applicable (NOT APPLICABLE)'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:04:18
Query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'Updated' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:45:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 18:19:59
User opened query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:11:42
User entered 'None (NONE)'	Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:26:25

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:52:06
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	18 Feb 2021 15:21:42
User entered '0' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	18 Feb 2021 15:21:33
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 01:44:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Jan 2021 20:46:57
User entered '1' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:46:57
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Dec 2020 21:26:25
User entered '0'	Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:26:25

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1' reason for change: Data Entry Error	(b) (4) amy sheets (b) (4)	18 Feb 2021 15:21:33
User entered '0'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:04:21
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:47:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:46:57
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:10:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stacey Saldua (b) (4) (b) (4)	22 Dec 2020 21:26:25

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) Stacey Saldua (b) (4)	22 Dec 2020 21:26:25
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:35
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per DM CLR: Narrative indicates that subject had "OXYGEN". However, this is not recorded in the Concomitant Medication eCRF. Review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:47:47
User closed query 'PV Query: Please confirm if thrombocytosis, elevated LFTs, and D-Dimer elevation meet criteria of AE/SAE. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 18:18:47
Query 'Per DM CLR: Narrative indicates that subject had "OXYGEN". However, this is not recorded in the Concomitant Medication eCRF. Review and record as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:24:38
Query 'PV Query: Please confirm if thrombocytosis, elevated LFTs, and D-Dimer elevation meet criteria of AE/SAE. ' answered with 'SAE has been completed for this event' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:23:52
User closed query 'PV Query: Per the case narrative, the subject had a positive COVID test at an outside facility on 06Dec2020, however per the DS, the diagnosis date was 02Dec2020. Please confirm the correct date of the first COVID test.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 15:04:31
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 15:04:27
Query 'PV Query: Per the case narrative, the subject had a positive COVID test at an outside facility on 06Dec2020, however per the DS, the diagnosis date was 02Dec2020. Please confirm the correct date of the first COVID test.' answered with 'updated' (Site from Safety).	Stacey Saldua (b) (4) (b) (4)	27 Jan 2021 20:49:42

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT DEVELOPED SYMPTOMS ON 11/27, TESTED POSITIVE FOR COVID 19 ON 6 DEC 2020 AND WAS HOSPITALIZED DUE TO DISEASE ON 9 DEC 2020, DISCHARGED HOME ON HOME OXYGEN ON 18 DEC 2020. SUBJECT INFORMED SITE OF HOSPITAL ADMISSION AND DIAGNOSIS 12:52 ON 06 DEC 2020.' reason for change: Data Entry Error	Stacey Saldua (b) (4)	27 Jan 2021 20:49:34
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'Updated' (Site from Safety).	Stacey Saldua (b) (4)	27 Jan 2021 20:47:37
User opened query 'Per DM CLR: Narrative indicates that subject had "OXYGEN". However, this is not recorded in the Concomitant Medication eCRF. Review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 04:53:07
User opened query 'PV Query: Please confirm if thrombocytosis, elevated LFTs, and D-Dimer elevation meet criteria of AE/SAE. ' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:12:41
User opened query 'PV Query: Per the case narrative, the subject had a positive COVID test at an outside facility on 06Dec2020, however per the DS, the diagnosis date was 02Dec2020. Please confirm the correct date of the first COVID test.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:12:26
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:08:30
User entered 'Subject developed symptoms on 11/27, tested positive for COVID 19 on 6 DEC 2020 and was hospitalized due to disease on 9 DEC 2020, discharged home on home oxygen on 18 DEC 2020. Subject informed site of hospital admission and diagnosis 12:52 on 22 Dec 2020.'	Stacey Saldua (b) (4)	22 Dec 2020 21:26:25

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 21:26:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 21:26:25

US3052315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 21:26:25

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'USA-US117-2020-mRNA-1273-P301000005'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:02:31

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 05:19:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 05:19:57
Data point term sent to Coder	System	22 Apr 2021 19:18:44
User entered 'bilateral PNEUMONIA DUE TO covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 19:17:48
Data point term sent to Coder	System	22 Apr 2021 14:58:22
User entered 'Pneumonia due to Novel coronavirus POA'	(b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:32:09
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	26 Apr 2021 18:48:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 18:48:51
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	26 Apr 2021 18:48:08
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 18:48:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 18:48:08
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:04:21
User entered '0'		22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:48:51
User entered '0'	System	26 Apr 2021 18:48:08
User entered '1'	System	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 14:57:38

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'USA-US117-2020-mRNA-1273-P301000005'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:06

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 15:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Apr 2021 15:00:58
Data point term sent to Coder	System	22 Apr 2021 15:00:24
User entered 'acute respiratory failure with hypoxia'	(b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	23 Apr 2021 13:52:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Apr 2021 15:02:36
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Apr 2021 15:02:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 15:02:36
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Apr 2021 15:00:16
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 15:00:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 15:00:16

US3052315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 15:00:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 15:00:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'USA-US117-2020-mRNA-1273-P301000005'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:26:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytoses, PT: Thrombocytosis, LLT: Thrombocytosis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 19:17:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 19:17:55
Data point term sent to Coder	System	22 Apr 2021 19:16:43
User entered 'thrombocytosis'	(b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:23
DataPoint Verified.	(b) (4)	26 Apr 2021 20:32:09
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 19:24:15
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	26 Apr 2021 19:24:15
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	22 Apr 2021 19:15:45
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	22 Apr 2021 19:16:28
User entered '1' reason for change: Data Entry Error	System	22 Apr 2021 19:16:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 19:15:45
User entered '0'	System	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:09
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 19:15:45

US3052315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:24

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

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 19:15:45

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:59:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:19:07
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:45:37
User closed query 'Per ETRTR: Please add medications and procedures done at Hospital for OCIVD-19 event if these were given, thanks.' (Site from CRA).	(b) (4)	04 Mar 2021 20:45:34
Query 'Per ETRTR: Please add medications and procedures done at Hospital for OCIVD-19 event if these were given, thanks.' answered with 'updated' (Site from CRA).	Stacey Saldua (b) (4)	28 Jan 2021 19:46:18
User opened query 'Per ETRTR: Please add medications and procedures done at Hospital for OCIVD-19 event if these were given, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 23:30:32
User entered 'Yes (Y)'	(b) (4)	02 Sep 2020 12:09:25

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 19:02:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 19:02:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 09:48:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 09:48:40
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:23:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:23:50
Data point term sent to Coder	System	02 Sep 2020 12:10:41
User entered 'Turmeric'	(b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Chronic back pain'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'UN Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 16:01:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 16:01:55
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	19 Oct 2020 16:01:55
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:10:20
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 12:10:20

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Jan 2021 12:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Jan 2021 12:04:27
Data point term sent to Coder	System	28 Jan 2021 19:48:52
User entered 'zinc'	Stacey Saldua (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Sars-cov-2'	Stacey Saldua (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'unk'	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Jan 2021 19:48:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 19:48:44
User entered 'mg (mg)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	28 Jan 2021 19:48:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Jan 2021 19:48:07
User entered empty.	System	28 Jan 2021 19:48:07
	Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'unknown (UNKNOWN)'	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Oral (ORAL)'	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	28 Jan 2021 19:48:17
User entered '08 Dec 2020' reason for change: Data Entry Error	System	28 Jan 2021 19:48:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Stacey Saldua (b) (4)	28 Jan 2021 19:48:17
User entered '08 Dec 200' (non-conformant).	(b) (4)	28 Jan 2021 19:48:07
	System	28 Jan 2021 19:48:07
	Stacey Saldua (b) (4)	28 Jan 2021 19:48:07
	(b) (4)	

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) Stacey Saldua (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 03:06:47
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'it is considered ongoing for now' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:40:42
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 05:29:56
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	Stacey Saldua (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 03:07:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:44:57
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 15:44:49
		28 Feb 2021 02:36:41
	Stacey Saldua (b) (4) (b) (4)	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 19:48:07

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:18:06
User closed query 'Please update source with information accurately. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:18:05
Query 'Please update source with information accurately. ' answered with 'updated source' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 19:35:09
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User opened query 'Please update source with information accurately. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:02:22
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:53:52
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:44:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:44:30
Data point term sent to Coder	System	04 Mar 2021 15:50:22
User entered 'oxygen'	(b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'SARS-COV-2'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User closed query 'Per CDM: Dose per administration should be "UNK" if data is Unknown as per CCG's. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:27:16
Query 'Per CDM: Dose per administration should be "UNK" if data is Unknown as per CCG's. Please update accordingly.' answered with 'updated' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	12 Mar 2021 18:52:54
User entered 'UNK' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	12 Mar 2021 18:52:47
User opened query 'Per CDM: Dose per administration should be "UNK" if data is Unknown as per CCG's. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 16:47:40
User entered 'unknown'		04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'liters'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:02:26
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 15:50:03

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:00:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:00:41
Data point term sent to Coder	System	22 Apr 2021 19:23:57
Data point term sent to Coder	System	22 Apr 2021 19:21:55
User entered 'dexamethasone'	(b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'thrombocytosis'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:32:34
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 19:01:00
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 19:01:00
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'unk' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:23:50
User entered '6'	(b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:32:34
Signature has been broken.		26 Apr 2021 19:01:00
User entered 'mg (mg)' reason for change: Data Entry Error		26 Apr 2021 19:01:00
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:23:50
User entered 'mg (mg)'		22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:32:34
Signature has been broken.		26 Apr 2021 19:01:00
User entered empty; reason for change Data Entry Error		26 Apr 2021 19:01:00
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	22 Apr 2021 19:25:23
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 19:25:23
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	22 Apr 2021 19:23:50
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:32:34
Signature has been broken.		26 Apr 2021 19:01:00
User entered 'once daily (QD)' reason for change: Data Entry Error		26 Apr 2021 19:01:00
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:23:50
User entered 'once daily (QD)'		22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Intravenous Drip (INTRAVENOUS DRIP)' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 19:23:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '09 Dec 2020' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 19:23:50
User entered '18 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4)	(b) (4)
User entered '21 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 19:23:50
		22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User entered '1'	System	26 Apr 2021 19:01:00
User entered empty.	System	22 Apr 2021 19:23:50
User entered '1'	System	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User entered '1'	System	26 Apr 2021 19:01:00
User entered empty.	System	22 Apr 2021 19:23:50
User entered '1'	System	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:27
User entered '804 (804)'	System	26 Apr 2021 19:01:00
User entered empty.	System	22 Apr 2021 19:23:50
User entered '804 (804)'	System	22 Apr 2021 19:21:08

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 02:44:42
Data point term sent to Coder	System	22 Apr 2021 19:30:06
User entered 'remdesivir'	(b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'covid-19'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '100'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:32:34
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
User entered '1'	System	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
User entered '1'	System	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:31:30
User entered '804 (804)'	System	22 Apr 2021 19:29:14

US3052315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:59:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:02
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered 'No (N)'	(b) (4) Avia McClain-Stocker	20 Oct 2020 15:11:51
	(b) (4)	

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:24

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '23/Dec/2020 05:53'	(b) (4) System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered '1'		23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:24

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '28/Dec/2020 14:30'	(b) (4) System	28 Dec 2020 14:30:21

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:31:54
User entered '1'		28 Dec 2020 14:30:21

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '28/Jan/2021 09:31'	(b) (4) System	28 Jan 2021 14:31:48

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:31:54
User entered '1'		28 Jan 2021 14:31:48

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '18/Feb/2021 21:38'	(b) (4) System	18 Feb 2021 21:38:28

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:19:07
User entered '1'		18 Feb 2021 21:38:28

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:59:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
User entered '05/Mar/2021 12:19'	(b) (4) System	05 Mar 2021 18:19:24

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:59:24

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)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:32:27
User entered '1'		05 Mar 2021 18:19:24

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:59:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '22/Apr/2021 15:04'	(b) (4) System	22 Apr 2021 19:05:11

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:59:24

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)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:05:11

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:59:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered '23/Apr/2021 09:27'	(b) (4) System	23 Apr 2021 13:27:45

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:59:24

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)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:27:45

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'USA-US117-2020-MRNA-1273-P301000005'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yes (Y)'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Yes (Y)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'No (N)'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Yaa'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Judith'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
Un-reviewed for Safety.	System	22 Apr 2021 19:02:31
DataPoint Un-verified.	System	22 Apr 2021 19:02:31
Signature has been broken.	System	22 Apr 2021 19:02:31
User entered 'Oppong'	System	22 Apr 2021 19:02:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:52:58
User entered 'Borger'	System	23 Dec 2020 13:52:37

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '1565 Purdue Drive'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'Fayetteville'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered 'NC'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:09:54
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:04:38
User entered '28314'	System	22 Apr 2021 19:02:31

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:46:48
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:30:13
User entered 'US'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:23:46
User entered '7'	System	23 Apr 2021 13:27:45
User entered '6'	System	22 Apr 2021 19:05:11
User entered '5'	System	05 Mar 2021 18:19:24
User entered '4'	System	18 Feb 2021 21:38:28
User entered '3'	System	28 Jan 2021 14:31:48
User entered '2'	System	28 Dec 2020 14:30:21
User entered '1'	System	23 Dec 2020 13:53:06

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:59:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 13:41:04
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:27:19
User entered '27/Apr/2021 07:23'	(b) (4) System	27 Apr 2021 14:23:46

US3052315

Folder: SAE USA-US117-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:59:24

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)	29 Apr 2021 13:41:04
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 12:27:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:23:46